CHEMICALS IN FOODS AND COSMETICS

HEARINGS

BEFORE THE

HOUSE SELECT COMMITTEE TO INVESTIGATE THE USE OF CHEMICALS IN FOODS AND COSMETICS

HOUSE OF REPRESENTATIVES

EIGHTY-SECOND CONGRESS

SECOND SESSION

PURSUANT TO

H. Res. 74 and H. Res. 447

(Continuing investigation and study begun under H. Res. 323, 81st Cong., 2d sess.)

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CONTENTS*

Statement of—

	Page
American Dental Association's Council on Dental Therapeutics, Chicago, Ill	1674
American Public Health Association	1738
Andervont, H. B., Ph. D., Chief of Laboratory of Biology, National Cancer Institute, Bethesda, Md	1665
Arnold, Francis A., Jr., D. D. S., National Institutes of Health, Bethesda, Md	1626, 1664
Association of State and Territorial Health Officers	1693
Ast, David B., D. D. S., M. P. H., representing the American Public Health Association	1738
Baer, Rudolf L., M. D., 962 Park Avenue, New York, N. Y	1163
Baldwin, Horace S., M. D., 136 East Sixty-fourth Street, New York, N. Y	1073
Barbasol Co., Indianapolis, Ind	1344
Beech-Nut Packing Co., Canajoharie, N. Y	1385
Behrman, Howard T., M. D., 2 East Sixty-ninth Street, New York, N. Y.	1149
Blayney, J. R., D. D. S., professor, dental surgery, director of the Walter G. Zoller Memorial Clinic, University of Chicago	1545
Bristol-Myers Co., 630 Park Avenue, New York, N. Y	1209
Colgate-Palmolive-Peet Co., 105 Hudson Street, Jersey City, N. J	1224
Conway, Bernard J., assistant secretary of the American Dental Association's Council on Legislation, Chicago, Ill	1674
Coty, Inc., 423 West Fifty-fifth Street, New York, N. Y	1293
Cox, L. G., Ph. D., Beech-Nut Packing Co., Canajoharie, N. Y	1385
Crawford, C. W., Commissioner of Food and Drugs, Food and Drug Administration, Federal Security Agency	1710
Curley Co., Inc., 1432 North Randolph Street, Philadelphia, Pa	1091
Dean, H. Trendley, D. D. S., National Institutes of Health, Bethesda, Md	1639, 1664
Dorosy Sales Corp., 489 Fifth Avenue, New York, N. Y	1333
Doty, J. Roy, Ph. D., secretary, American Dental Association's Council on Dental Therapeutics, Chicago, Ill	1674
Elizabeth Arden Sales Corp., 681 Fifth Avenue, New York, N. Y	1252
Fairfield Laboratories, Inc., Plainfield, N. J	1115
Forsyth, Bruce D., D. D. S., Assistant Surgeon General, Chief Dental Officer, U. S. Public Health Service	1483, 1635, 1664
Fuller, George H., plant manager, Harriet Hubbard Ayer and Lever Bros. Co., 505 Park Avenue, New York, N. Y	1259
Gershon, Sol D., Ph. D., representing Lever Bros. Co., 505 Park Avenue, New York, N. Y	1265
Giles, I. V., chief chemist, representing Primrose House, Inc., 420 Lexington Avenue, New York, N. Y., and the Barbasol Co., Indianapolis, Ind	1344
Goldzieher, Max A., M. D., representing Hirestra Laboratories, Inc., 745 Fifth Avenue, New York, N. Y	1141
Grolnick, Max, M. D., 555 Ocean Avenue, Brooklyn, N. Y	1320
Hansen, Fred H., plant manager, Hirestra Laboratories, Inc., 745 Fifth Avenue, New York, N. Y	1144
Harriet Hubbard Ayer, 505 Park Avenue, New York, N. Y	1259
Harris, Robert S., Ph. D., Nutritional Biochemistry Laboratories, Department of Food Technology, Massachusetts Institute of Technology	1513

*A cumulative alphabetical list of all persons who either appeared or submitted statements during the entire course of the select committee's hearings, from September 13, 1950, through March 6, 1952, and a cumulative subject matter index for the same period will be printed under a separate cover.

Statement of—Continued Page

Hart, E. B., Sc. D., professor of biochemistry, University of Wisconsin, Madison, Wis 1564
Helena Rubinstein, 633 Fifth Avenue, New York, N. Y 1168
Herrmann, Charles A., chief, New York district, United States Food and Drug Administration, New York, N. Y 1289
Herrmann, Mrs. Dorothy, representing Dorosy Sales Corp., 489 Fifth Avenue, New York, N. Y 1333
Heyroth, Francis F., M. D., representing National Research Council Ad Hoc Committee on Fluoridation 1764
Hines, Don Carlos, M. D., Conarroe Road, New Augusta, Marion County, Ind., and Eli Lilly & Co., and Wick & Fry 1418, 1428
Hirestra Laboratories, Inc., 745 Fifth Avenue, New York N. Y 1123
Hueper, Wilhelm C., M. D., 8495 Rockville Pike, Bethesda, Md 1353
Hurme, V. O., D. D. S., director of clinical research, Forsyth Dental Infirmary for Children, Boston, Mass 1575
Jolliffe, Norman, M. D., representing the New York Academy of Medicine, 2 East One Hundred and Third Street, New York, N. Y 1301
Klarmann, Emil G., chief chemist, Lehn & Fink Products Corp., 192 Bloomfield Avenue, Bloomfield, N. J 1269
Knutson, John W., D. D. S., Division of Dental Public Health, United State Public Health Service 1493, 1625, 1664
Kremer, George, Jr., president, Roux Laboratories, Inc., 1841 Park Avenue, New York, N. Y 1180
Larson, Carl, Ph. D., chemist, Elizabeth Arden Sales Corp., 681 Fifth Avenue, New York, N. Y 1252
Lehn & Fink Products Corp., 192 Bloomfield Avenue, Bloomfield, N. J 1269
Lever Bros. Co., 505 Park Avenue, New York, N. Y 1265
Levin, Franklin, president, Curley Co., Inc., 1432 North Randolph Street, Philadelphia, Pa 1091, 1097
Lilly & Co., Eli, 740 South Alabama Street, Indianapolis 6, Ind 1418
Lubowe, Irwin I., M. D., 1 West Eighty-fifth Street, New York, N. Y 1312
Maas & Waldstein, 438 Riverside Avenue, Newark, N. J 1198
Magnus, Robert, treasurer and factory manager, Maas & Waldstein, 438 Riverside Avenue, Newark, N. J 1198
Martin, Jean, chief chemist, Coty, Inc., 423 West Fifty-fifth Street, New York, N. Y 1293
Masters, Edward J., Ph. D., factory manager, Helena Rubinstein, 633 Fifth Avenue, New York, N. Y 1168
Mayer, R. L., M. D., 52 Mountain Avenue, Summit, N. J 1337
National Research Council Ad Hoc Committee on Fluoridation 1764
Neumann, Hans H., M. D., 1377 Kew Street, Hewlitt, N. Y 1593
New York Academy of Medicine, 2 East One Hundred and Third Street, New York, N. Y 1301
Peck, Samuel M., M. D., 33 East Seventieth Street, New York, N. Y 1235
Pillsbury, Donald M., M. D., professor of dermatology, University Hospital, University of Pennsylvania School of Medicine, Philadelphia, Pa 1104
Porterfield, John D., M. D., secretary-treasurer, representing the Association of State and Territorial Health Officers 1693
Powers, Donald H., Ph. D., research director, Richard Hudnut, 113–127 West Eighteenth Street, New York, N. Y 1216
Primrose House, Inc., 420 Lexington Avenue, New York, N. Y 1344
Pyenson, Louis, Ph. D., entomologist, Long Island Agricultural and Technical Institute, Farmingdale, Long Island, N. Y 1286
Rakoff, Abraham E., M. D., 269 South Nineteenth Street, Philadelphia, Pa 1193
Revlon Products Corp., 745 Fifth Avenue, New York, N. Y 1327
Rheinstrom, Robert I., representing Hirestra Laboratories, Inc., 745 Fifth Avenue, New York, N. Y 1123
Richard Hudnut, 113–127 West Eighteenth Street, New York, N. Y 1216
Rounds, Wellington, president, Fairfield Laboratories, Inc., Plainfield, N. J 1115
Roux Laboratories, Inc., 1841 Park Avenue, New York, N. Y 1180
Russell, Kenneth L., Ph. D., chemist, Colgate-Palmolive-Peet Co., 105 Hudson Street, Jersey City, N. J 1224

Statement of—Continued Page
Sevringhaus, Elmer L., M. D., director of endocrinology and metabolism, Medical Center, Jersey City, N. J. 1306
Sharlit, Herman, M. D., 32 East Sixty-fourth Street, New York, N. Y. 1277
Smith, Howard V., associate agricultural chemist, University of Arizona, Tucson, Ariz. 1614
Smith, Margaret Cammack, Ph. D., former head, department of human nutrition, University of Arizona, Tucson, Ariz. 1602
Soroko, Mark D., general service manager, Revlon Products Corp., 745 Fifth Avenue, New York, N. Y. 1327
Sulzberger, Marion B., M. D., 999 Fifth Avenue, New York, N. Y. 1055
Taylor, Alfred, Ph. D., Biochemical Institute, University of Texas, Austin, Tex. 1529
Walzer, Matthew, M. D., 20 Plaza Street, Brooklyn, N. Y. 1248
Wick & Fry, Inc., Cumberland, Ind. 1418
Wickenden, Leonard, industrial chemist, Sturges Highway, Westport, Conn. 1077
Wolcott, George L., M. D., medical director, Bristol-Myers Co., 630 Park Avenue, New York, N. Y. 1209
Zipkin, Isadore, Ph. D., National Institutes of Health, Bethesda, Md. 1643
Letters, statements, articles, etc., submitted for the record by—
American Medical Association Committee on Cosmetics, statement of R. T. Stormont, M. D. 1721
American Medical Association, statement submitted by George F. Lull, M. D., secretary and general manager, February 27, 1952, on fluoridation of community water supplies. 1709
Bristol-Myers Co., statement by Dan Dahle, 630 Park Avenue, New York, N. Y. 1736
Chemicals in Cosmetics, address by S. L. Mayham, Toilet Goods Association, Inc., January 23, 1952. 1730
Dangers of Cosmetics and the Testing Methods by Which Such Dangers Can Be Foretold, memo by Adolph Rostenberg, Jr., M. D. 1800
Effect of Foods Grown in Different Areas on the Prevalence of Dental Caries and Hamsters, article from Archives of Biochemistry, volume 26, No. 1, March 1950. 1525
Endocreme—a Cosmetic With a Menace, article from the Journal of American Medical Association, April 9, 1938. 1134
Endocrine Laboratories, Madison, Wis., Roland K. Meyer, consultant, report, Extraction and biological assay of beef and chicken tissues for estrogenic activity, etc. 1437
Fluoridation of water supply in the prophylaxis of dental caries, its effectiveness and safety, by Dr. Francis F. Heyroth, report to the Cincinnati Board of Health. 1787
Fluoridation of water supplies, statement of Journal of American Medical Association, December 1, 1951. 1488
Food and Drug Administration, Associate Commissioner John L. Harvey, letter to Vincent A. Kleinfeld, chief counsel, Select Committee on Chemicals, September 13, 1951. 1710
Haldi, Dr. John, School of Dentistry, Emory University, letter to Hon. James J. Delaney, January 17, 1952. 1465
Heinz Co., H. J., letter to Hon. James J. Delaney, November 8, 1950. 1416
Hirestra Laboratories vs. American Medical Association, article from the Journal of American Medical Association, April 20, 1940. 1137
Hormones in Cosmetics Harmless—Doctors' Prog. memo compiled by R. I. Rheinstrom. 1127
Interindustry Conference on Chemicals in Food, article by Dr. R. C. Newton, vice president, Swift & Co., January 15, 1952. 1408
Manufacturing Chemists' Association, article, Approach to Proposed Changes in Present Law. 1796
Manufacturing Chemists' Association, Inc., Charles S. Munson, chairman, board of directors, letter to Hon. James J. Delaney, February 5, 1952, with enclosures. 1471
Crawford, C. W., remarks of, Commissioner of Food and Drugs, the Food and Drug Administration's viewpoint on chemicals in food. 1472
Dow Chemical Co., remarks of G. J. Williams, on present law and proposed changes. 1481

Letters, statements, articles, etc.—Continued Page
Manufacturing Chemists Association, etc. Inc.—Continued
Quaker Oats Co., remarks of Dr. F. N. Peters, Jr., vice president, chemical research, on legislative controls on research and development in foods 1478
Metabolism of fluorine, statement regarding his experiments, by F. J. McClure, biochemist, National Institute of Dental Research, Bethesda, Md 1672
Miscellaneous letters regarding cosmetic injuries submitted by C. W. Crawford, Commissioner of Food and Drug Administration 1727
National Cotton Council of America, William Rhea Blake, executive vice president, letter to Hon. James J. Delaney, October 16, 1951 1471
National Institutes of Health, Norman Topping, associate director, letter to Dr. Robert F. Korns, director, bureau of epidemiology and communicable disease control, State of New York Department of Health, May 17, 1951 1679
New England Journal of Medicine article from vol. 244, page 361, March 8, 1951, entitled, The Caries-Producing Effect of Similar Foods Grown in Different Soil Areas 1526
Newton, Roy C., vice president, Swift & Co., letter to Vincent A. Kleinfeld, chief counsel, January 22, 1952, with enclosed statement 1407
Nuckolls, James, College of Dentistry, University of California, letter to Hon. James J. Delaney, January 17, 1952 1463
Pretesting Cosmetics Before Distribution and Submitting Such Testing Data for Approval to the Food and Drug Administration, article by Louis Schwartz, M. D 1797
Scheele, Leonard A., Surgeon General, Public Health Service, letter to Hon. James J. Delaney, January 2, 1952, with enclosure 1383
Status of Cosmetics Containing Hormones, article from the Journal of American Medical Association, June 16, 1945 1136
Summary Comments on Fluorine—Its Occurrence, Use, and Hazards, article by I. Zipkin and H. T. Dean with F. J. McClure 1661
Summary of investigation on DDT residues on foods and DDT storage in human fat, report from Communicable Disease Center, Public Health Service, Savannah, Ga 1383
Wick V. Fry, Inc., Cumberland, Ind., results of tests for estrogenic substance in the tissues 1438

CHEMICALS IN FOODS AND COSMETICS

THURSDAY, JANUARY 10, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE USE
OF CHEMICALS IN FOODS AND COSMETICS,
New York, N. Y.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess.; continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 10:10 a. m., in room 128, United States Courthouse, New York, N. Y., Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney of New York, Abernethy of Mississippi, Hedrick of West Virginia, Jones of Missouri, and McDonough of California.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will be in order.

Gentlemen, it is a privilege and a pleasure for me, a native New Yorker, to welcome you to our great city. I trust that your stay may be an enjoyable one, an informative one, and an interesting one.

The subject to be taken up today, in furtherance of the select committee's investigation into the use of chemicals in food products, is the matter of cosmetics and their effect upon human health. A number of both industry and medical experts have been requested to appear, and we will start our proceeding without further delay.

Call your first witness.

Mr. KLEINFELD. Dr. Sulzberger.

The CHAIRMAN. Your name, sir, and address?

Dr. SULZBERGER. Marion B. Sulzberger. My office address is 999 Fifth Avenue, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed, Mr. Kleinfeld.

TESTIMONY OF MARION B. SULZBERGER, M. D., NEW YORK CITY

Mr. KLEINFELD. Dr. Sulzberger, from what school did you get your medical degree?

Dr. SULZBERGER. The University of Zurich, Switzerland.

Mr. KLEINFELD. In what year?

Dr. SULZBERGER. Nineteen twenty-six.

Mr. KLEINFELD. Are you a fellow of the American Medical Association?

Dr. SULZBERGER. I am.

Mr. KLEINFELD. How long have you practiced medicine, Doctor?

Dr. SULZBERGER. Since 1929.

Mr. KLEINFELD. And how long have you specialized in the field of dermatology?

Dr. SULZBERGER. Since 1926.

Mr. KLEINFELD. Are you a professor of dermatology and syphilology at New York University, Bellevue Medical Center?

Dr. SULZBERGER. New York University Postgraduate Medical School, which is part of that center.

Mr. KLEINFELD. Of what societies are you a member?

Dr. SULZBERGER. The American Dermatological Association, the Society for Investigative Dermatology, the Academy of Allergy, numerous others—including many foreign societies. I am an honorary member of British, many European, Australian, South American, and other foreign societies.

Mr. KLEINFELD. Have you contributed papers in the field of dermatology to the professional publications?

Dr. SULZBERGER. I have.

Mr. KLEINFELD. About how many papers, would you say?

Dr. SULZBERGER. Over 200; about 250, perhaps.

Mr. KLEINFELD. All in the field of dermatology?

Dr. SULZBERGER. All in the field of dermatology, syphilology, and related subjects in medicine.

Mr. KLEINFELD. And you are now practicing dermatology?

Dr. SULZBERGER. I am.

Mr. KLEINFELD. Will you please read your statement, Doctor.

Dr. SULZBERGER. I would first like to say, like Congressman Delaney, I am very happy to be here, being a native New Yorker also.

Mr. KLEINFELD. We thank you for coming.

Dr. SULZBERGER. Being neither a legislator nor a lawyer, my statements are made without any pretense as to special knowledge concerning the adequacy of existing legislation nor concerning the writing or enforcing of laws in general. My expressions of opinion are based purely on clinical experience as a specialist in skin diseases and as one who has had particular interest in the investigation of allergic dermatoses and the possible beneficial and possible harmful effects of various cosmetics.

1. The first question I think I should discuss is: What number of untoward effects should be permitted; that is, what degree of tolerance ought a law on cosmetics include in regard to possible incidence of harm?

The above question is predicated upon the incontrovertible fact that there is probably no agent which can be used with impunity by each and every human being; and that every cosmetic or other agent to which the human skin is exposed has the potential capacity for creating harmful effects in some of the almost infinitely large number of conceivable users. To paraphrase Lincoln's famous words: When it comes to cosmetic damage you can protect some of the people all of the time; you can protect all of the people some of the time; but you can't protect all of the people all of the time. It is therefore essential to make provision for a possible and allowable incidence of harmful effects, as otherwise every preparation would have to be banned.

Here one is faced with the first of a series of major difficulties in seeking to protect the public. It is certainly not possible for any agreement to be reached regarding a general over-all figure of per-

missible incidence of harmful effects for all and any cosmetics. Should 1 case of damage in 5,000 users or 1 in 10,000 or 1 in 100,000 or only one in a million or hundred million users be tolerated? The answer to questions of this sort must depend entirely upon such circumstances as the type and severity of damage, the duration of the damage, the correctability of the damage, the seriousness, the permanence, or evanescence of the changes consequent or secondary to the damage, et cetera.

The decisive influence of such modifying circumstances is brought out clearly when one considers, for example, on the one hand the possibility of 1 death in every 5,000 users or 1 case of scarring and disfigurement of the face in every 5,000 users—as contrasted with 1 case of ephemeral hives or 1 case of a transient poison-ivy-like dermatitis in every 5,000 users.

My conclusion is therefore that the incidence of damage which should be tolerated from a given cosmetic preparation must be decided in each particular instance with due consideration for the specific cosmetic or class of cosmetics and its specific type or kind of damage; and that no general figure of over-all tolerance can be specified in any law or regulation applicable to all kinds of cosmetics and all sorts of damage.

2. The second question I should like to discuss is as follows: Is it possible to specify what tests should be carried out beforehand in order to estimate or predict the safety of a given cosmetic preparation for public use?

My answer to this statement must, unfortunately, be: "No; it is not possible." No available test and no group or battery of known tests can possibly fortell with any satisfactory degree of accuracy the potential damage which may ensue when a given cosmetic preparation is introduced for use among a very large number of consumers. When one devises tests which may be applicable, for example, to the assaying of a new lipstick—a form of cosmetic which will be applied on the average of three times a day, 365 days a year, and some part of which is inevitably ingested—one cannot expect the same tests to be applicable also for the assaying of a new face powder which is applied several times daily but is inevitably inhaled; nor can the same tests be equally useful in assaying an eyelash dye or a shampoo which is used on the average of once weekly but may then often get into the eyes. How could one conceivably establish tests equally suitable for assaying the potential damage of cosmetics such as hair sets or wave-setting lotions which may be applied once weekly; permanent-wave lotions which may be used twice or thrice a year; nail lacquers which are applied mainly to the hard nail-plates; and cold creams and lubricating creams which are rubbed into the softest parts of the skin? Or how can it be expected that the same kinds of tests should be adequate to estimate potential damage from a material which is applied several times daily by the inexperienced individual user and a material which is applied only occasionally by trained hands in a registered beauty parlor? Moreover, how could the same sorts of tests be expected to indicate potential acute damage—which can occur within a few minutes, hours, or days after use—and also to indicate potential chronic damage or long-delayed ill effects which may appear only many years after the last exposure or only after repeated and continued use over a long period of years?

Or is it conceivable that any batteries of tests could be specified which would be equally adequate to disclose the possible incidence of temporary local contact dermatitis, of scarring, of photosensitization, of blinding, of cancer production, of absorption and kidney or liver damage—to name but some of the various forms of damage which have been known to result from various applications to the human skin. I have here mentioned only a few of the facts which show that when one speaks of "testing cosmetics", one is speaking of testing a tremendous number of widely diverse agents, differing from one another in their purposes of use; sites of applications; manners, numbers, quantities and intervals of exposures; and in their types, kinds, degrees and severities, permanence and transience of potential ill effects.

It is therefore my conclusion that no law or regulation can specify in general the types of preliminary testing to which each new cosmetic should be subjected; but that each newly introduced preparation must be subjected to tests specially designed by experts and considered adequate for that particular agent, its constituents and ingredients, its intended manner of use and its estimated, a priori, potentialities for producing specified and particular kinds of harmful effects.

Despite this obvious necessity for particularization in testing, I believe that some general principles can perhaps be formulated for testing new cosmetics intended for use upon the human skin and its appendages. Among the tests based on these general principles one should in each instance consider the inclusion of the following:

(*a*) Tests for primary irritancy in which the new material X is compared with several widely sold, well-established cosmetics which have been in general use for the same or similar purposes. The tests are carried out by applying the new agent X to a site on the skin of an adequate number of volunteers who are simultaneously exposed in other skin sites and in similar fashion to applications of the old established analagous cosmetics A, B, and C, for example. In this manner a ratio of primary irritancy of X to A, X to B, and X to C can be ascertained. If these ratios of irritancy equal one or less than one it can be inferred that the new material probably has no more primary irritancy than the old established cosmetics sold to the public for similar purposes.

(*b*) In similar fashion to (*a*), the sensitizing capacity of X should be compared with that of old established preparations having similar cosmetic uses. This can be done first by ascertaining the relative sensitizing potentials by application to guinea pigs' skins; and then by ascertaining relative sensitizing potentials in experimental sensitizations in human volunteers—establishment of the "sensitizing index."

(*c*) In order to rule out systemic toxicity through absorption, et cetera, of materials applied to the human skin, toxicity experiments of classic type should be performed on suitable laboratory animals by injection, ingestion, inhalation, inunction, inoculation, et cetera, of the new product under consideration.

(*d*) Even when all of the above tests have indicated the relative safety of the new product in comparison with old established ones, whenever the formula or ingredients suggest that the new product constitutes a radical departure from old preparations and represents

an indubitable new risk, the sale of the new product should at first be restricted to selected communities on a trial basis. This trial should be sufficiently long and the numbers of users sufficiently great to permit at least a fair estimation of potential acute damage when the product is employed under conditions of its intended use in very much larger numbers of users. Such a preliminary trial in restricted numbers of communities would have not only the public health advantage of preventing the unfortunate precipitate release of a damaging product to an unlimited population of consumers, but would also be advantageous to the introducers of new products by limiting the costs and financial damages resulting from their inadvertent introduction of a harmful agent as well as limiting the degree of damage to their reputations.

3. Registry and identification of all new cosmetics and their ingredients: I believe that the above statement represents something which a law could well demand. When one considers the hundreds of millions of users of cosmetics of all kinds, the untold billions of applications of these agents to the human hair, skin, eyes, lips, and orifices in general, it appears to me that the public welfare requires that the exact formulae and the common accepted names of the ingredients of these materials be submitted to a central governmental agency. This agency would then have the information available and accessible to all those with legitimate interests—for example, to physicians interested in studying cases of potential or proven damage, to consumers who know of their hypersensitivity to certain ingredients of cosmetics, et cetera. I believe that a "new cosmetic application" should be required, much like the required "new drug application," but that the governmental agency enforcing the law should make the decision as to whether any formula submitted really constitutes a newly introduced agent or combination—or simply a minor modification or duplication of an old cosmetic formula. When, after careful study, a cosmetic formula is adjudged to be new, suitable tests should be required along the lines specified under 2, and with due consideration of the manner of use, quantity to be applied, intervals between applications, sites of intended and of probable accidental exposure, and with due regard for the particular kinds of potential acute or chronic damage which might be expected on the basis of what is known concerning the immunobiologic and toxicologic properties of the particular preparation and of each of its ingredients.

4. Number of untoward effects to be tolerated under the law: In reverting to the topic I first discussed under section 1, I do so in order to call attention to the fact that once it can be decided that the material or the expected damage is such as to make a certain incidence of possible untoward effects permissible or tolerable under the law, this will indicate the numbers of tests which must be applied in order to ascertain with a specified percentage of probability the number of untoward effects to be expected in a population of a given size. The following tables indicate the numbers of tests required under each particular set of statistical and numerical conditions:

TABLE 1.—*Number of subjects required, if there are no positives in the sample to predict with a 95 percent or 99 percent likelihood that the population rate does not exceed certain designated values (noted in left-hand column)*

Maximum permissible percentage of reaction in population	Required number of subjects for likelihood of—		Maximum permissible percentage of reaction in population	Required number of subjects for likelihood of—	
	95 percent	99 percent		95 percent	99 percent
0.01	29,978	46,083	1.0	298	459
0.1	2,994	4,603	2.0	148	228
0.5	597	918	3.0	98	151

Source: C. R. Henderson and E. C. Riley, Certain Statistical Considerations in Patch Testing, Journal of Investigational Dermatology, 6:227–230, June 1945.

TABLE 2.—*Upper limit of positive reaction rate estimated for the population, with a 95 percent likelihood, from results of 0, 1, or 2 positives in a sample of designated size (noted in left-hand column)*

Number of subjects in sample	Likely maximum rate of positive reactions in large number			Number of subjects in sample	Likely maximum rate of positive reactions in large number		
	With no reaction in sample	With 1 reaction in sample	With 2 reactions in sample		With no reaction in sample	With 1 reaction in sample	With 2 reactions in sample
	Percent	*Percent*	*Percent*		*Percent*	*Percent*	*Percent*
30,000	0.01			200	1.5	2.2	2.9
20,000			0.03	160			3.7
10,000	.03	0.05	.06	150	2.0	3.0	
5,000	.06	.09		125	2.4	3.6	
4,000			.15	120			4.9
2,000	.15	.23	.30	100	3.0	4.4	5.8
1,000	.30	.45		80	3.7	5.5	7.3
800	.37	.56	.75	60	4.9	7.3	9.6
600	.50	.75	1.0	50	5.8	8.8	
500			1.2	40	7.2	10.8	14.0
400	.75	1.1	1.5	30	9.5	14.2	
300	.99	1.5	2.0	20	13.9	20.8	27.0
250	1.2	1.8	2.4	10	26.9	38.2	

Source: C. R., Henderson, and E. C. Riley: Certain Statistical Considerations in Patch Testing, Journal of Investigational Dermatology, 6:227–230, June 1945.

TABLE 3.—*The theoretical probabilities of getting no reactors, 1 reactor, and more than 1 reactor for 3 assumed population rates*

Number of subjects in group	Probability of getting			Number of subjects in group	Probability of getting		
	No reactor	1 reactor	More than 1 reactor		No reactor	1 reactor	More than 1 reactor
	Population value=0.25 percent				Population value=0.1 percent—Continued		
50	0.88	0.11	0.01	800	0.45	0.36	0.19
100	.78	.19	.02	2,000	.14	.27	.59
200	.61	.30	.09		Population value=0.01 percent		
400	.37	.37	.26				
800	.14	.27	.59	50	0.995	0.005	0.000
2,000	.01	.03	.96	100	.990	.010	.000
	Population value=0.1 percent			200	.980	.020	.000
				400	.961	.038	.001
50	0.95	0.049	0.001	800	.923	.074	.003
100	.90	.09	.01	2,000	.819	.164	.017
200	.82	.16	.02				
400	.67	.27	.06				

Source: L. F. Knudsen: A Note on the Statistical Probabilities of Finding Hypersensitive Subjects in Random Samples, Journal of Investigational Dermatology, 6:231–232, June 1945.

Dr. SULZBERGER. Mr. Kleinfeld, I don't think I can read these tables, but if I may, I would like to just read one group of figures that is pertinent from what I have seen in previous testimony before the committee.

Mr. KLEINFELD. Go right ahead, Doctor.

Dr SULZBERGER. One hears a great deal about the witching figure of 200 patch tests, or 200 tests which are to be applied beforehand. In the purely statistical and numerical compilation which was compiled by Henderson and Riley you find that if one takes a random sample of 200 persons—a sample which is representative of a given population—if one finds that there is no reaction to a given test (which duplicates the conditions of exposure to be expected in the population at large) if there are no reactions in the 200 of the sample, one has a 95 percent likelihood—that the reaction in the population at large will not be over 1.5 percent. In other words, that is 1½ percent out of a total population, 1½ person out of every hundred, or 3 persons out of every 200. That is all one can say when these tests are all negative in the sample of 200—there is a 95 percent likelihood that in the population at large no more than 3 people in every 200 will be damaged by that substance applied in that manner—which, of course, is a tremendously high percentage of damage to be expected, even when they are all negative, these 200 sampling tests.

The CHAIRMAN. Is that what is commonly known as a patch test?

Dr. SULZBERGER. Yes. This would apply to any form of testing. This would apply even if you would pull 200 balls, let's say, out of a glass fish bowl known to contain both black and white balls, as in drawing lots. If in your first 200 balls you pulled out only white—if in the first 200 you pulled out none of the black ones but only white ones—then you could say with 95 percent probability that the bowl didn't contain more than 1½ percent black balls. That applies to any kind of testing. It is just a purely mathematical, statistical figure, but it would apply to the number 200 usually advocated for patch testing, as well.

Mr. MCDONOUGH. In other words, are you saying the patch testing now in use is not conclusive enough with respect to the damage the cosmetic may do?

Dr. SULZBERGER. The numbers are very inadequate for that purpose.

Mr. MCDONOUGH. What would you recommend to make it more accurate and more comprehensive?

Dr. SULZBERGER. Well, of course, the greater the sample you test, the more accurate you become. Even that never suffices. That is why I have included in this prepared statement, the fact that I advocate usage tests or field trials, and many additional things which must be done. But I just want to point out at this point—I want to emphasize at this point that the number 200 is not magic; and that even when all tests are negative in that sample of 200, all one can say is that the probability is that the population will not be damaged in more than 1.5 percent of users. That is all you could possibly conclude from that sample. And that is assuming that the conditions of the tests were exactly the same as the conditions of use—which, of course, they never are.

5. Summary and Inferences: In closing, I believe that the above statements make it unfortunately clear that no law and no regulation

under the law can be expected to do more than demand two things: First, that a registry be kept of the ingredients of each cosmetic preparation, that the exact formulae and pertinent information on each cosmetic preparation be submitted and recorded; and second, that the manufacturers and introducers of new preparations be required to submit the records of preliminary tests and trials which must be particularized in each instance according to the circumstances applicable to the particular preparation and the potential damages which might be expected from its constitution and properties and under its conditions of use.

Since there are so many variables in these circumstances and conditions, it is easy to understand why there are so many differences of opinion among experts, skin specialists, and others, as to just how cosmetics should be tested and just how many tests of each kind should be performed and required. Obviously, one expert may be thinking of tests adequate for a face powder, another of tests suitable for assaying irritancy or sensitization from a hair dye, a third of preliminary testing suitable for "hormone creams," et cetera. In my judgment, most of the expert opinions I have read or heard have been correct when considered in relation to a particular kind of cosmetic and a particular class of potential damages—but none has been correct for, or applicable to, all the vast diversity of kinds of cosmetic preparations and the almost unlimited varieties and often unpredictable sorts of potential damage.

If the public is to be protected from most of these, there must be provisions for particularization, individualization, and flexibility of screening tests devised by competent experts; as well as the submission and registry of the complete information on each and every cosmetic and its ingredients.

Thank you.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Sulzberger, in your statement you discuss various tests. I am talking about the paragraph entitled "Is it possible to specify what tests should be carried out beforehand?", and so on. It is the second major heading of your statement.

Dr. SULZBERGER. I see.

Mr. KLEINFELD. And you say this:

> When one devises tests which may be applicable, for example, to the assaying of a new lipstick, one cannot expect the same tests to be applicable also for the assaying of a new face powder which is applied several times daily but is inevitably inhaled; nor can the same tests be equally useful in assaying an eyelash dye or a shampoo which is used on the average of once weekly but may then often get into the eyes.

In putting out a shampoo preparation, would you recommend that the manufacturer of the shampoo first test the shampoo in an animal's eyes?

Dr. SULZBERGER. I must confess that before I knew about certain incidents—incidents which I think have recently come to the attention of everyone here now—I don't know whether it would have occurred to me to advise the manufacturer to put a shampoo into the eye. It certainly should have, because if we thought for a moment we should realize that persons shampooing their hair—even I, when shampooing my few hairs—might get some of the shampoo into my eyes. Think how much more likely for all the gentlemen I see before me to get

shampoo into their eyes, and a lady with longer hair to get it into her eyes. I have never been consulted by a manufacturer regarding the pretesting of shampoos; and I don't know whether I would have thought of advising a test by inoculation or exposure of the eyes of experimental animals.

Mr. KLEINFELD. And it would be even more likely, if the shampoo were used for children, would it not?

Dr. SULZBERGER. I suppose so, if they shampoo themselves.

Mr. KLEINFELD. In the paragraph following that which I just read, you say:

> Or is it conceivable that any batteries of tests could be specified which would be equally adequate to disclose the possible incidence of temporary local contact dermatitis, of scarring, of photosensitization, of blinding, of cancer production, of absorption and kidney or liver damage—to name but some of the various forms of damage which have been known to result from various applications to the human skin.

Do I gather correctly from what you say, Doctor, that some of the damage, in your experience, has been perhaps minor in character and some has been rather serious?

Dr. SULZBERGER. From my own experience and from what I know from reading and hearing about the experience of others, I would say that all of the things which I have specified here have been observed by me or reported to me on good authority and are established.

Mr. KLEINFELD. So that the problem is a rather serious one; is it not?

Dr. SULZBERGER. It can be very serious. I would say that the milder forms of damage are by far the most common, but the serious ones, although rare, do occur.

Mr. KLEINFELD. Dr. Sulzberger, you speak in your statement of certain types of testing. You say:

> I believe that some general principles can perhaps be formulated for testing new cosmetics intended for use upon the human skin and its appendages.

Do you believe that it is necessary, for the protection of the public, that tests of that general character be carried out?

Dr. SULZBERGER. I think so; yes, for new preparations.

Mr. KLEINFELD. And what may occur if those tests or similar tests are not carried out for new preparations?

Dr. SULZBERGER. Well, if no pretesting was done on new preparations, some of them would surely cause damage to human beings that could have been prevented by preliminary testing. No preliminary testing will insure with absolute certainty that there will be no damage to any user whatsoever, but the incidence of damage to users can be reduced by proper preliminary testing. Does that answer your question?

Mr. KLEINFELD. Yes.

Suppose a manufacturer is putting out a cosmetic preparation which has been used for some time, and a change is made in the formula. Might that present a new problem, requiring new testing, new experimental work?

Dr. SULZBERGER. Yes.

Dr. KLEINFELD. Who is going to judge whether the patch tests, and use tests, and all the experimental work are adequate to conclude that the product is safe? Are you going to leave that to the judgment of each particular cosmetic manufacturer or distributor?

Dr. SULZBERGER. That, of course, is one of the most difficult questions to answer. It has so many facets. There is a legal aspect to it, there is an enforcement aspect to it, and the question of authority, which is very difficult to weigh in answering that question, What authority has a State or the United States in regard to such requirements? There are all kinds of things in connection with this question which go way beyond my own knowledge and my capacity to answer properly.

But I would say that I think this problem in relation to new cosmetics is closely related to, if not almost identical with, the problem in relation to new drugs; that the public is being exposed to these materials in the same way that they are being exposed to drugs and to foods and the responsibility therefore for safeguarding the public must be divided in the same way. Surely there is a certain responsibility on the part of the manufacturer not to release agents which he knows might be harmful to the public. Certainly there is a responsibility on the part of every governmental agency—municipal, State, Federal—to safeguard the citizens from the knowing or unknowing release of harmful agents for the public use.

And if you want me to be specific instead of answering your question in general as to who should do it——

Mr. KLEINFELD. As a dermatologist, and thinking of the protection to which the public is entitled.

Dr. SULZBERGER. I envisage it in this way: If there is a list of cosmetics which has been established as being relatively safe by years of use and millions of applications, cosmetics that are similar or closely analogous to or identical with those which have been in use can be regarded as safe. You establish a sort of safe list, like we know about what aspirin will do today and what talcum will do today.

Mr. KLEINFELD. Is it possible that ingredient A may be generally regarded as safe, and similarly ingredient B may be regarded as safe, but the combination of the two may create a different problem?

Dr. SULZBERGER. That is right.

Mr. KLEINFELD. Quite a different problem.

Dr. SULZBERGER. You have to consider the ingredients, the individual constituents, the combinations, and the entire product. Then again a material may be safe for one use and unsafe for another use. So you have to consider the conditions of use and exposure.

Mr. KLEINFELD. Thus, if a cosmetic is recommended for use in the region of the hair, I suppose the careful cosmetic manufacturer might think of the possible consequences if the product approaches the orbital area; is that correct?

Dr. SULZBERGER. That is correct.

Mr. KLEINFELD. In the tests you mention as being fairly reasonable tests, is it necessary that a qualified expert read and judge the results of the experimental work carried on?

Dr. SULZBERGER. Decidedly so.

Mr. KLEINFELD. Ordinarily, who would such an expert be?

Dr. SULZBERGER. Well, there are different types of tests, so there are different experts. For patch tests, certain specially trained and qualified dermatologists are probably the only ones qualified to read them for primary irritancy and sensitivity of the skin. I think that dermatologists are the only ones qualified. And on animal experi-

mentation regarding systemic toxicity, toxicologists, pharmacologists, and people of that kind are the only competent ones.

Mr. KLEINFELD. People that are trained in that field?

Dr. SULZBERGER. In the special fields, and there are several special fields involved in this testing.

Mr. KLEINFELD. Have you had any experience, Doctor, in trying to ascertain, in the course of some particular problem you have had, just what is in a particular cosmetic?

Dr. SULZBERGER. Yes; I have.

Mr. KLEINFELD. Have you read the labels?

Dr. SULZBERGER. Well, the labels don't indicate what is in them very often.

Mr. KLEINFELD. Would it have helped you if they did?

Dr. SULZBERGER. It certainly would. But I would like to add something to that answer.

Mr. KLEINFELD. All right.

Dr. SULZBERGER. I think it is impossible to ask things which are impossible of manufacturers, and to create laws or regulations which cannot be observed. And it is impossible to put all the ingredients in a lipstick upon a lipstick container. It may have 60 or a hundred or more ingredients, and even when you use the smallest kind of print that is still legible, you couldn't get them all on.

Mr. KLEINFELD. That seems to be a real problem, Doctor.

Dr. SULZBERGER. Yes.

Mr. KLEINFELD. What would you think of this—suppose the law provided that a list of all the ingredients in a cosmetic should be submitted to some Government agency, and that the label should contain a listing of ingredients subject to the issuance of regulations by the agency making such exceptions as are necessary to meet the practical situation which you mention. Do you think that might meet the situation?

Dr. SULZBERGER. Well, except that I think that you would find that there would be more exceptions than there would be conformity to the rule. In other words, I think most cosmetic containers couldn't very well carry the printed matter that is necessary for this. And then there is the question of selecting what should be on the container and what should not be on it. The things which many people call bland or innocuous or not active agents sometimes are the worst offenders in relation to allergy.

Mr. KLEINFELD. Inactive?

Dr. SULZBERGER. Yes; the ones you call inactive, like lanolin or ointment bases of various kinds can cause trouble when people are allergic to them. So the distinction between active and inactive agents becomes difficult.

Mr. KLEINFELD. So you think that to meet the practicalities of the situation with which we have to live, the answer might be a submission of quantitative and qualitative formulas to a governmental agency?

Dr. SULZBERGER. That is why in my prepared statement I deliberately omitted the recommendation as to placing the list of all ingredients on the packages or containers. Maybe one should ask that they should be placed on the large bulk packages which are sent to the jobbers. That might be something. I don't know. But I think the individual package of the cosmetic, the little vial of that perfume which may contain a hundred ingredients——

Mr. KLEINFELD. How about setting out the ingredients on a little circular, not attached to the bottle, but in the carton or container?

Dr. SULZBERGER. I can't see any objection to that.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Hedrick.

Dr. HEDRICK. Doctor, what is your opinion of the use of estrogenic hormones in face cream. Do you think it is safe?

Dr. SULZBERGER. Well, I have a very definite opinion about that, Dr. Hedrick. I think today that in the concentrations in which they are put into face creams the record to date shows they have been entirely safe.

I had a different opinion 6, 8 or 10 years ago. I thought that they were very risky. I thought that on the one hand they had possibilities of damaging the skin and that on the other hand there was no evidence that they could achieve any possible benefits so far as appearance was concerned; and I had to change my mind in both directions. It is possible, I believe, to put in a quantity of estrogenic hormones in face creams which cause some plumping out of the skin on repeated application, and it is still possible to have that concentration so low that the risks of damage are almost disappearing, are negligible.

Dr. HEDRICK. You mean to say it might relieve some of the wrinkles that people have in their face?

Dr. SULZBERGER. It causes a mild degree of diffuse swelling.

Dr. HEDRICK. Kind of an edema?

Dr. SULZBERGER. It is called edema; yes—plumping of the tissues by retaining of more water. It isn't actually free fluid like in a blister, but it is fluid distributed and held in the tissue.

Dr. HEDRICK. Do you believe there is a possibility they might cause precanceroses?

Dr. SULZBERGER. Not any longer.

Dr. HEDRICK. You did believe that at one time?

Dr. SULZBERGER. I did.

Dr. HEDRICK. And now you think they are perfectly safe?

Dr. SULZBERGER. Yes; and I sat recently on a special committee under Dr. Goodfriend and Dr. Corwin, of the New York Academy of Medicine, to discuss that very problem. I was the dermatologist, Dr. Goodfriend was the gynecologist, and the endocrinologist was Dr. Shorr, and there were on the committee several pharmacologists and other experts. And we reviewed the evidence very carefully, and reviewed also a communication from, I think it was Dr. Durrett—is that right?

Mr. KLEINFELD. Yes.

Dr. SULZBERGER. We had a statement from him as well, and we came to the conclusion that there was not any evidence today available of any formation of cancer or precanceroses or any damage from the estrogens as applied in cosmetic creams. And all the available evidence was in the opposite direction, that they did no harm and no systemic damage of any kind. Even on theoretical grounds the dosage of hormone was so small in these estrogenic creams a person would have had to apply five packages a day, 10 ounces a day, in order to get enough absorption to cause any systemic effect.

Mr. JONES. In other words, the advertising that the companies are putting out on that cream, is really leaving an incorrect impression; is that right?

Dr. SULZBERGER. No; I don't think that is right. My opinion is—I haven't read all the advertising of all these companies—of course, the advertising of comestics anyway is quite a blown-up affair in general. There is a grain of truth in it and the rest is just a lot of words. But by and large I would say that I, myself, have never with my own eyes seen that a woman who had been using one of these creams for 6 years looked any younger 6 years later, but she always looked 6 years older to me after 6 years of use——

Mr. JONES. I mean in some of these advertisements, don't they leave the impression that some kind of biological change might take place in addition to the appearance created on the surface?

Dr. SULZBERGER. Well, I suppose the ads say that the use of the creams will make them look more youthful. I don't remember the wording of these ads, but from my vague recollections they say the creams make a person look more youthful, and I guess the plumping out of the skin does that.

Mr. JONES. I have one other question. You said a moment ago you would have no objection to including a list of ingredients on a folder or insert in the package. Well, would there be any benefit that would result from that?

Dr. SULZBERGER. It would make my life much easier and the lives of other physicians who are constantly confronted by people who are allergic to some ingredient and at present cannot tell them which cosmetics they may or may not use.

Mr. JONES. The benefit would come to the patient if she knew she were allergic to a certain thing and could avoid using a product which contained that ingredient?

Dr. SULZBERGER. That is correct.

Mr. JONES. In your experience, have you encountered any fatalities you can attribute to the use of cosmetics?

Dr. SULZBERGER. Not in my own experience.

Mr. JONES. In your practice, have you had people who were permanently disfigured from the use of cosmetics according to the directions that the manufacturer recommended?

Dr. SULZBERGER. No; I don't recall having seen anyone permanently disfigured and in whom the disfigurement was proven due to cosmetics. However, I have seen people disabled for very long periods of time, months to years.

Mr. JONES. In what way were they disfigured?

Dr. SULZBERGER. With skin eruptions and falling-out of hair and itching and generalized skin eruptions—for example from dyes.

Mr. JONES. Is it your opinion that most people, when they use a hair dye, for instance, know they are taking a certain risk or hazard in using that preparation?

Dr. SULZBERGER. Most of the intelligent people today, the intelligent and informed women today, know they are taking a certain risk.

Mr. JONES. And they are willing to take that risk in order to have the possibility of obtaining a certain result?

Dr. SULZBERGER. Most of them are; yes.

Mr. JONES. And has it been your observation that most of these preparations do include on the package certain precautions that should be taken?

Dr. SULZBERGER. Yes; they do.

Mr. JONES. I think that is all I have.

The CHAIRMAN. Mr. McDonough.

Mr. MCDONOUGH. Doctor, do you believe that it is necessary to incorporate into these cosmetics these detrimental chemicals and dyes in order to obtain the results they claim will be obtained?

Dr. SULZBERGER. Well, I think that there is no such thing as a substance which is not potentially detrimental to some percentage of users. If there are such substances, they must be very rare. In other words, there is nothing that is inevitably and always innocuous to everyone.

There are certain of the ingredients at present continually used in cosmetics which are known to have a much higher potentiality of sensitizing and of doing harm than others; and even such ingredients with the higher sensitivity capacity, the higher sensitizing index, must be included in order for the cosmetics to be salable and to achieve their effects.

For example, lipstick. When people get allergic reactions from lipstick, in most instances it is the indelible dye which is the responsible allergen. In other words, a nonindelible lipstick would cause less damage than the indelible ones; and still the manufacturers who know that very well are compelled to include the indelible dyes because if they made their lipsticks nonindelible they couldn't sell them competitively with the lipsticks with indelible dyes.

Mr. MCDONOUGH. That means they do that in order to meet competition?

Dr. SULZBERGER. That is right.

Mr. MCDONOUGH. So someone started it some place along the line, and as a result of that all other manufacturers use it in order to compete?

Dr. SULZBERGER. That is right.

Mr. MCDONOUGH. In your opinion how many of the cosmetics that are now on the market—we will include in that category those that are well-established and well-known of all classifications, shampoos, hair dyes, lipsticks and creams, and other things—are potentially detrimental to the human system? Would you say there are 10 percent of those that are on the market which are detrimental, 5 percent, or what percent?

Dr. SULZBERGER. If you include the cosmetics that contain sensitizing agents that may cause damage in a very exceptional instance, then I would say 100 percent of them are potentially damaging. If you mean a high incidence of damage or severe damage, then I would say a very negligible percentage of them are harmful. In other words, those that can cause toxic effects or those that can cause lasting damage or those that will cause irritation or sensitization to a high percentage of users, irritations or allergic reaction of the skin, are very, very few.

Mr. ABERNETHY. Will the Congressman yield there?

Mr. MCDONOUGH. Yes.

Mr. ABERNETHY. What would you say with reference to serious damage? What percentage?

Dr. SULZBERGER. I can't express it in percentage.

Mr. ABERNETHY. Would you say it would be negligible or not?

Dr. SULZBERGER. Yes; I think serious damage is of negligible incidence.

Mr. McDONOUGH. That is, your answer is based on the user following the instructions of the manufacturer for the cosmetic. You wouldn't say if a person bought a lipstick and ate it and became inoculated with a dye——

Dr. SULZBERGER. I think they could eat it.

Mr. McDONOUGH. If I bought a shampoo and drank it, that would not be following the instructions of the manufacturer.

Dr. SULZBERGER. No.

Mr. McDONOUGH. You mean if they use it as a manufacturer outlines on the label?

Dr. SULZBERGER. Even if they didn't, Mr. McDonough, I think most cosmetics would be harmless, even eating them. It is a very peculiar situation. There are some dyes you can eat and which are still not safe to put on the skin. Some of the certified food dyes were the worst skin sensitizers; and, of course, vice versa, there are some things you can put on the skin but not eat.

Mr. McDONOUGH. Has the use of these highly sensitizing chemicals, the allergenic ingredients in cosmetics, become more general in the last 5 or 10 years—or what period of time? As I recall, there was very little question about the danger of the use of cosmetics when I was a youngster, but it is becoming quite a problem now.

Dr. SULZBERGER. I published the first dermatologic article devoted to the use of the patch tests in this country, and just before I came here I looked up the date because I was interested in that, and it has some bearing on your question. That was in 1931. Before that it had never been consistently or scientifically used in the United States. It is only since that time it has come into general use. Let's say, 20 years. So that the awareness of these allergic reactions to cosmetics has been growing tremendously, and also the use of cosmetics has been growing tremendously. I think those two things together—the tremendous increase in the numbers of exposures and the tremendous increase in the awareness and reporting and publication of sensitizations and damage—those two together I think account for the increased incidence of recorded damage rather than an increasing number of really harmful agents being put into the various cosmetics. On the contrary, I think that the really harmful agents in cosmetics, really harmful toxic chemicals, have been gradually, or rapidly eliminated. There are no longer any cosmetics with arsenic, there are none of them any more with lead, and so forth.

Mr. McDONOUGH. In other words, is that the result of the public reporting these cases or is it the result of a greater number of dermatologists?

Dr. SULZBERGER. I would like to take all the credit for the dermatologists—but I don't think I can. I think again that the removal of toxic ingredients and potentially damaging agents is a result of various forces. One such force, I think, is the competitive economic situation. The cosmetic manufacturers simply can't stand for much talk about damage from their cosmetics or from a particular agent. That plus the awareness on the part of both the public and the medical profession plus the more general reporting of the cases and their scientific study—those three things combined I think have resulted—as well as governmental supervision in the Food and Drug Administration and so forth, and of course what you gentlemen are doing—all the potential legislation, if not actual legislation—all of that accounts

for the reduction of harmful substances in cosmetics and acts as a brake upon putting potentially harmful things out and helps to keep them off the market.

From my point of view, the unfortunate part is that if these suggestions or recommendations which I have voiced and which others have voiced are adopted, they will not be a hardship upon large but only upon small manufacturers. Most large cosmetic concerns are now doing almost everything I have suggested, if not everything—for instance, as in my written statement, they do field trials and also test out new cosmetics on their factory and office employees for weeks or months before releasing them. But the carrying out of all these testing specifications, if such regulations or laws are adopted, would be a hardship upon the small manfuacturer.

Mr. McDONOUGH. The possible damage to the human system applies more to the female than the male; does it not?

Dr. SULZBERGER. Because she uses more cosmetics.

Mr. McDONOUGH. The woman uses more cosmetics?

Dr. SULZBERGER. Oh, she is much more exposed; yes, sir.

Mr. McDONOUGH. Have you run into many cases where men are affected?

Dr. SULZBERGER. Yes.

Mr. McDONOUGH. Largely from shampoos and hair applications, or what?

Dr. SULZBERGER. Yes. A good deal of it is like, I think, your own case. You have a sensitivity to a hair lotion; have you not?

Mr. McDONOUGH. I have had.

Mr. ABERNETHY. You mean you can tell from there?

Mr. McDONOUGH. That is interesting. Can you tell from there?

Dr. SULZBERGER. No. [Laughter.]

Mr. McDONOUGH. You have been reading the testimony, I guess.

Dr. SULZBERGER. Beg pardon?

Mr. McDONOUGH. Did you get that out of the hearings of the committee?

Dr. SULZBERGER. Yes; and I know about Mrs. Jones' allergy and about yours, Mr. Jones.

Men, of course, get into cosmetic difficulties mainly from the things they use, but they don't get into trouble exclusively from the things they themselves use. People get into difficulty also from things others use.

For instance, I have seen men with lipstick dermatitis from their wives' lipstick, or eruptions from their wives' nail polish—sometimes very interesting ones.

Mr. KLEINFELD. Necessarily from their wives?

Dr. SULZBERGER. No. [Laughter.]

Mr. KLEINFELD. I have one or two more questions.

Do you know which types of cosmetic preparations contain hormones?

Dr. SULZBERGER. Which types contain hormones?

Mr. KLEINFELD. Yes.

Dr. SULZBERGER. I don't know if I know all of them. I know that mainly creams contain hormones.

Mr. KLEINFELD. If the situation is, as I understand it to be, that there are creams which contain hormones, which are ordinarily applied before a woman goes to bed and thus will remain on her skin

for a considerable period of time, and there are oils or lotions which are applied during the day which also contain hormones, and if the preparations are also recommended for use on the neck, throat, hands, elbows, shoulders, hair, and scalp, would that present in your opinion a different problem?

Dr. SULZBERGER. No. That was the thing which I looked into before I made my statement. Would you like to hear some figures about the relationship between the amount which could be absorbed that way and the amount which could be systemically damaging?

Mr. KLEINFELD. If you could do it in a brief period of time; yes.

Dr. SULZBERGER. Yes; I can do it quite quickly. Cosmetic creams that have come to my attention, and from the best information I could get, contain about 10,000 international units per ounce. That is the average top figure. According to the work of several authors—for example, of Dr. Goldzieher and his coworkers—about 6,000 international units per ounce suffices to produce local demonstrable changes in the skin which might well be considered beneficial purely from the point of view of the appearance of the skin. And, according to Shorr, who is probably the greatest authority in this field today, it would require the application to the skin of about 100,000 international units per day to produce the mildest systemic changes. So they would have to use, as I said before, about 10 ounces of the cream per day, no matter where they spread it or where they put it—and that is almost an impossibility.

Mr. KLEINFELD. Is it a fact that there is a different problem which may need further surveying, depending upon the areas of the body upon which the cosmetics are applied?

Dr. SULZBERGER. No. They can't get any more of the hormone in than is present in the cream they are applying, no matter how widespread their applications or how often. I do admit there is a difference between giving the hormones to people to use without any control, without any limitation as to the amount which they could use, between this and prescribing the hormones for them for a specfic use under medical supervision and for treatment. But I think that it is fortunate for the situation and for the manufacturers and for the public that the ratios here seem to be so favorable that even the utmost top limit of use to which women could put these cosmetic creams doesn't seem to enable a woman to put enough on her skin or rub in enough per day to produce systemic damage.

Mr. KLEINFELD. And do you know whether any clinical work has been done upon the basis of which conclusions can be reached—clinical work where various cosmetic preparations containing the amounts of international units which you mentioned were used? I understand hormones are used in all these types of cosmetics for considerable periods of time, day after day. Do you know whether any actual clinical work has been done?

Dr. SULZBERGER. Well, if you mean clinical work in the sense of deliberately reinvestigating these people systematically to find out what has happened to them, then I would say I don't know of any such long-term studies.

Mr. KLEINFELD. How about on animals?

Dr. SULZBERGER. I am not up on the literature of the animal experiments in this field. But if you mean clinical observations, I have some which I have carried out now for 6 years on my patients. They

have had no striking changes that could be attributable to the use of these cosmetic hormone creams where they have used them on their skin. I haven't seen that they looked any younger, but none of them have shown signs of any serious damage to their skin nor reported any other damage—no menstrual disturbances and no endocrinological changes.

Mr. KLEINFELD. I gathered from what you said that the patients you observed were using hormones in face cream. You don't know whether they were using other types?

Dr. SULZBERGER. All those I saw were using them in creams.

Mr. KLEINFELD. Just the creams?

Dr. SULZBERGER. Yes.

Mr. KLEINFELD. And you said you don't know of any actual animal work or whether biopsies have been performed?

Dr. SULZBERGER. You mean after the application of these hormones?

Mr. KLEINFELD. After the application of these hormones in these various types of preparations which I have mentioned, over a considerable period of time.

Dr. SULZBERGER. No; I don't—after various preparations over a considerable period of time.

Mr. KLEINFELD. Doctor, is it a fact there are new substances or chemicals being used in cosmetics from time to time?

Dr. SULZBERGER. Yes.

Mr. KLEINFELD. For example, a lot of wetting agents?

Dr. SULZBERGER. Yes.

Mr. KLEINFELD. I want to read you one statement furnished this committee by the Food and Drug Administration, and ask if that highlights the problem which I think you specified in your statement. Here is what the letter from the Food and Drug Administration to this committee says, and it has nothing to do with hormones:

> About 8 or 9 years ago, the styles in hair arrangements for women resulted in a widespread adoption of what has been facetiously called the "washerwoman hairdo," which involved piling the hair on top of the head and arranging it neatly so that it would remain in such an arrangement for an indefinite period. Among the esthetic draw-backs to this hair arrangement were those stray locks on the back of the neck which did not conform to the arrangement and were left dangling in a more or less untidy effect. To meet the crying need thus created, an immediate popularity developed for some kind of adhesive material which would affix these stray locks in an upward direction and attach them to the remainder of the upswept hair. To fill this need a Chicago manufacturer created "Locks-Up Hair Lacquer Pads." These were in the form of a cotton pad impregnated with a lacquer substance which, when pressed upward around the hairdo increased the tidiness of the arrangement by glueing the hair to the rest of the arrangement. In applying the lacquer pads they necessarily came in contact with the skin and scalp adjacent to the hair.
>
> This development occurred during wartime when there was a scarcity of lacquer materials, shellac, varnish, resins, and glue. Apparently the first product was entirely successful and created an enormous demand. Subsequent batches of manufacture employed unknown, untested adhesive materials, synthetic resins, et cetera, and the result of that hasty improvising was that hundreds of women throughout the United States suffered significant injury by reason of the poisonous nature of the resins used, which created a contact dermatitis and other painful and disfiguring complications. As a result of regulatory activity of this Administration, the product was eventually removed from the market, but not until a great deal of damage had occurred.

Now is that the type of situation which may result from an improper testing, careless or negligent testing, or no testing at all, and is that the sort of thing you think we ought to do something about?

Dr. SULZBERGER. Yes; and I think it could be avoided in a great measure, not always but almost always, by proper testing.

Mr. KLEINFELD. No further questions.

The CHAIRMAN. Thank you, Doctor, for your contribution. We are indebted to you for coming here today.

Dr. SULZBERGER. Thank you very much.

The CHAIRMAN. Call your next witness.

Mr. KLEINFELD. Dr. Baldwin.

The CHAIRMAN. Your name and address?

Dr. BALDWIN. Horace S. Baldwin, 136 East Sixty-fourth Street, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed, Mr. Kleinfeld.

TESTIMONY OF HORACE S. BALDWIN, M. D., NEW YORK, N. Y.

Mr. KLEINFELD. Dr. Baldwin, of what medical school are you a graduate?

Dr. BALDWIN. Cornell University.

Mr. KLEINFELD. When did you graduate, Doctor?

Dr. BALDWIN. 1921.

Mr. KLEINFELD. And you have practiced medicine since then?

Dr. BALDWIN. After my internship; yes.

Mr. KLEINFELD. I see. And your specialty is in the field of allergy?

Dr. BALDWIN. That is right.

Mr. KLEINFELD. How long have you specialized in that field?

Dr. BALDWIN. Since 1925.

Mr. KLEINFELD. Are you a member of the American Academy of Allergy?

Dr. BALDWIN. Yes.

Mr. KLEINFELD. And you are associate professor of clinical medicine at Cornell University Medical School?

Dr. BALDWIN. That is right.

Mr. KLEINFELD. And you are certified in that specialty by the American Board of Internal Medicine?

Dr. BALDWIN. I am.

Mr. KLEINFELD. Read your statement, please.

Dr. BALDWIN. In the past, serious injury to users of certain cosmetics has occurred because of failure to conduct tests and submit data to the Food and Drug Administration. Thallium acetate, lead, and mercury in various cosmetics caused a number of toxic symptoms before their use was prohibited by law. It would seem advantageous to have a law which would require the manufacturer of a new and untried cosmetic to submit it to the Food and Drug Administration for survey and necessary testing before it is marketed. Here it could be surveyed from the standpoint of its systemic toxicity, its primary irritating qualities and its allergenic possibilities, and necessary tests done if indicated.

From the allergic standpoint serious reactions may occur when a person allergic to certain substances uses cosmetics containing them. It would be helpful to the allergic person if the law required a listing of ingredients on the label, and at the same time it would be helpful to the physician treating such a patient if such information were available.

I agree with the views expressed by Dr. Louis Schwartz, former Medical Director USPHS, in his article in Cooke's Allergy in Theory and Practice, Saunders, Philadelphia, 1947, page 282, under the heading "Dermatitis From Cosmetics."

The CHAIRMAN. Is that your statement?

Dr. BALDWIN. That is the extent of my statement.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Then, from the viewpoint of the allergist, you say that serious reactions may occur when a person who is allergic to certain substances uses cosmetics containing them?

Dr. BALDWIN. That is right.

Mr. KLEINFELD. And they may be more than minor in nature?

Dr. BALDWIN. They may.

Mr. KLEINFELD. For example, what may o cur?

Dr. BALDWIN. They may have a severe dermatitis, severe bronchial asthma, or a severe reaction in the nasal mucous membranes. The reaction may vary; it may be on the skin, it may be in the respiratory tract. Those are the places where these reactions may occur.

Mr. KLEINFELD. Again from the viewpoint of an allergist, you believe that rather careful testing should be employed before new ingredients or combinations of ingredients are employed in cosmetics?

Dr. BALDWIN. Yes, I do.

Mr. KLEINFELD. And also from the viewpoint of an allergist who comes in contact constantly with persons suffering from allergic reactions, you think it would be helpful to you and to the patient if consumers knew what was in the products they were buying?

Dr. BALDWIN. Yes.

Mr. KLEINFELD. In order that they would be in a position to avoid, in the future, buying those things containing substances which had caused these injuries; is that correct?

Dr. BALDWIN. That is right. And, on the other hand, should they have allergic reactions which might be attributable to cosmetics, the fact that they were labeled would make it possible to test for those things that they are using.

Mr. KLEINFELD. And suppose a woman is using a cosmetic, has been using it for a considerable period of time, and has had no adverse reactions. If the formula is changed so that different combinations of the ingredients are used in the cosmetic, that may cause untoward reactions, may it not?

Dr. BALDWIN. Yes; if she is sensitive to it.

Mr. KLEINFELD. But she has no way of knowing.

Dr. BALDWIN. She has no way of knowing; correct.

Mr. KLEINFELD. So that your recommendation, as far as what should be done to help protect the public from the viewpoint of an allergist, is:

It would seem advantageous to have a law which would require the manufacturer of a new and untried cosmetic to submit it to the Food and Drug Administration for survey and necessary testing before it is marketed.

Now, of course, if the facilities of the Food and Drug Administration are not sufficient, and I am sure they are not, to conduct actual testing of every preparation, what do you think of following generally the new drug type of procedure. This requires the manufacturer, the company which makes the new drug, to present his data to the Food and Drug Administration and say, "Here is what I have done.

They show, in my opinion, that the product is safe when used as suggested and recommended." And then the evaluation is performed by the Food and Drug Administration.

Dr. BALDWIN. I think that in general is what I have indicated—that the manufacturer should submit his formula to the Food and Drug Administration, and then the Food and Drug Administration by its experience with the various substances used in the various cosmetics would be able to indicate whether they thought more tests of certain types should be done.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Hedrick.

Dr. HEDRICK. I have no questions.

The CHAIRMAN. Mr. Jones?

Mr. JONES. I have a question.

Dr. Baldwin, I have noticed that different people are allergic to different types of food. For instance, some people cannot eat strawberries, some people cannot eat cucumbers, and things like that. In your practice, have you reached a conclusion or observed that any single food product creates a greater number of allergic reactions than other food products; in other words, we will say pork, or chocolate, or oranges, or something like that has a tendency to create a greater number of reactions in people generally than some other food product?

Dr. BALDWIN. I think one might say that, for instance, fish and shellfish cause a good many very severe reactions, probably more severe reactions than a great many other foods. In infants, you know, for example, egg white may cause a good deal of allergic disturbance.

Mr. JONES. What I am getting at along that line is this—I think you would agree it would not be practical for us to put a prohibition on that food being served in public places because it did create a greater reaction. That wouldn't be reasonable, would it—a regulation or a law to prevent that?

Dr. BALDWIN. I don't think so, no.

Mr. JONES. I was interested here in your statement where you say it would be advantageous to have a law which would require the manufacturer of a new and untried cosmetic to submit it to the Food and Drug Administration for survey and necessary testing before it is marketed. Have you given any thought to the possible or probable length of time that would be required before it would be established that a thing was not harmful to the public, how long those tests should be continued, and as to the number of tests, and if it is to be animal tests, how many different animals should be used or how many life cycles should be included?

Dr. BALDWIN. Mr. Jones, as far as I am concerned, I would not set myself up as an expert on the statistical necessities of such a matter. I have thought this over, and it seems to me that the Food and Drug Administration through their contact with chemists, pharmacologists, dermatologists, allergists, and statisticians would be able to answer your question if they gave thought and time to it.

For instance, there is a consulting committee now to the Food and Drug Administration consisting of representatives from the Academy of Allergy and College of Allergy. I should think such a committee would be of great help to the Food and Drug Administration in drawing up regulations for that type of testing.

Mr. JONES. Has it been your observation or experience that a number of people suffer from certain discomforts over a long period of time due to an allergy, and that after they have consulted a competent allergist, they can obtain immediate relief by refraining from the use of certain foods or the use of certain cosmetics or being around certain things that might be in the atmosphere; that that can usually be corrected by a change in diet or altering their customary practices; is that right?

Dr. BALDWIN. Yes; I think if they stop using the cosmetics to which they are sensitive, their symptoms are usually relieved.

Mr. JONES. And have you observed any permanent results that have existed following the discovery that a person was allergic to a certain cosmetic, but after they discontinued the use thereof, that they were not relieved of the discomfort?

Dr. BALDWIN. No; I would say that the effect, the allergic effect of these substances, is a temporary one. I have not observed permanent damage.

Mr. JONES. You have not observed any chronic, permanent injury from it then?

Dr. BALDWIN. I might qualify that to this point: that if a person were allergic to, we will say, orris root or cornstarch or rice powder that was in a cosmetic or a face powder, and he or she continued to use it over a long period of time, it is possible that changes might occur in the respiratory tract, the nasal sinus membranes, the bronchial mucous membranes, which would be irreversible.

Mr. JONES. But they would have gone through a rather long period of suffering and would have failed to have secured relief that would have been available to the average person by going to the average physician in a case like that, though, would they not?

Dr. BALDWIN. Well——

Mr. JONES. Maybe not the average physician. But if a person is going to have a chronic and lasting effect from a sinus or bronchial trouble, he would have experienced a discomfort during a rather long period of time before it would have come to the point where it was incurable. Would that be correct?

Dr. BALDWIN. Yes; I think that is true.

Mr. JONES. I have no more questions.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. What is there about shellfish that causes allergy in so many people, Doctor, do you know?

Dr. BALDWIN. No. It just happens that there are certain proteins that are much more allergenic than others, that seem to be more easily sensitizing agents than others, just like——

Dr. HEDRICK. Just like strawberries, for instance?

Dr. BALDWIN. Like ragweed, for instance, in the air. Ragweed is a very important sensitizing agent, and timothy grass is too, but not as active a sensitizing agent as ragweed. There are probably certain protein configurations that make one substance more allergenic than another.

The CHAIRMAN. Mr. McDonough?

Mr. MCDONOUGH. No questions.

Mr. KLEINFELD. One more question, Doctor. I do not know if you are familiar with this situation. It happened some time ago. But before the passage of the present Food, Drug, and Cosmetic Act in

1938, there was a product on the market called, I believe, Lash-Lure, which was supposed to beautify women's eyelashes. It sold for quite some time and in the great majority of instances it didn't create any harm. But in the case of a number of women it got into their eyes—naturally, because it was employed on the eyelash—and caused definite and permanent blindness. Might that have been an allergic reaction in those few women to that particular product?

Dr. BALDWIN. Yes; I think so.

Mr. KLEINFELD. That did happen. There were some women, not all by any means, in fact, a small minority, who were permanently blinded. That is a pretty serious problem, is it not?

Dr. BALDWIN. Yes.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Thank you, Doctor.

Call your next witness.

Mr. KLEINFELD. Mr. Chairman, I would like to call someone out of turn, since he is from out of town. It does not touch the cosmetic problem, it deals with fertilizers.

The CHAIRMAN. Very well.

Mr. KLEINFELD. Mr. Leonard Wickenden.

The CHAIRMAN. Your name and address, please.

Mr. WICKENDEN. Leonard Wickenden, Sturges Highway, Westport, Conn.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed, Mr. Kleinfeld.

Mr. KLEINFELD. Since your statement contains a brief biographical sketch, I suggest you read it.

TESTIMONY OF LEONARD WICKENDEN, INDUSTRIAL CHEMIST, WESTPORT, CONN.

Mr. WICKENDEN. My name is Leonard Wickenden. Throughout my adult life, I have been an industrial chemist. I received my scientific education at what is now known as the Imperial College of Science and Technology, of London, England. I graduated in 1906 and then took a postgraduate course in the chemistry of foods and drugs.

From 1908 to 1911, I was assistant chemist to the world-famous biscuit manufacturers, Huntley & Palmers, Ltd., of Reading, England. I then emigrated to this country and obtained a position in the electrochemical department of the West Virginia Pulp & Paper Co. In 1913, I was placed in charge of the research division of the New York laboratories of that company, and in 1918, when the laboratories were enlarged, I was appointed chief chemist with a staff of 20 working under my direction. In 1924, I was elected a fellow of the American Institute of Chemists and in 1926 I became vice president of the Suchar Process Corp., a company formed to exploit some of my patents, of which 26 have been granted by the United States Patent Office and others are pending.

In 1934 I started a consulting practice of my own with offices at 120 Wall Street, New York City. Since my early years I have been interested in the practice and theory of growing plants; at the end of 1949 I sold my laboratory and retired to my home at Westport, Conn., to devote whatever years remain to me to experimental agriculture and

the study of the soil. I am the author of a book entitled "Make Friends With Your Land," published by the Devin-Adair Co.

I have read much of the evidence presented to your committee on the subject of fertilizers and it has seemed to me that some of it has been—unintentionally, of course—confusing and self-contradictory. I hope I can help to clear up this confusion and I believe it can best be done by sharply defining the opposing views on this matter so that we can see to what extent they are in agreement and at what point their differences become acute.

Witness after witness has laid emphasis on the need for fertilizing farm land. On that point, it seems to me, there can be no difference of opinion and, as far as my experience goes, none exists. Throughout the ages, farmers have fertilized their soil; and only by so doing have they found it possible to produce good crops year after year, generation after generation. On this, all schools of thought are agreed; it is a waste of breath and of the time of your committee to labor the point. Confusion can arise only when the word "fertilizer" is used as though it were synonymous with "chemical fertilizer." Fertilization of the soil is very old; chemical fertilizers, in the long history of agriculture, are very new.

Neither is there any difference of opinion regarding the wisdom of adding minerals to a soil which is deficient in calcium, phosphates, potash, magnesia, or other elements. Some attempt seems to have been made to include lime in the group of chemical fertilizers. To do so can lead only to confusion. I have met or corresponded with a large number of so-called organic farmers, market gardeners, and home gardeners, both in this country and in Great Britain, but never have I encountered one who did not himself use, and advise others to use, lime in one form or another. Most of them prefer limestone to hydrated lime but I do not think such preference can be considered a fundamental of their creed. Similarly, such materials as phosphate and potash rocks, which always contain many additional trace elements, are widely used in the so-called organic method.

On the other hand, advocates of chemical fertilizers have, in recent years, greatly changed their views regarding the value of organic matter. Dr. William Ogg, head of the well-known Rothamsted Experimental Station in England, still maintains that wheat can be grown, year after year, on soil which receives nothing but chemical fertilizers, but he seems to be almost alone in his beliefs. Dr. Bear, in his statement of your committee, said:

> Organic matter is a very important part of a fertile soil and purely inorganic fertilizers will not take its place directly.

Dr. Bradfield stated:

> The maintenance of a good supply of organic matter in the soil is one of the basic objections of good soil management. The proper use of organic matter cannot be overestimated.

The National Fertilizer Association has published an advertising booklet entitled "Organic Matter—the Life of the Soil." In it, this statement occurs:

> Soils that are low in organic matter usually produce poor crops.

Yet, in almost the same breath that your witnesses have given such testimony, they have told you that there is not nearly enough organic matter to go around. Is that not a gospel of despair? If organic

matter is of prime importance, if good crops cannot be grown without it, but if the amount available is far short of our requirements, does it not follow that the human race faces inevitable starvation? If it is true that there is an incurable lack of organic matter, we can look forward only to a steady decline in the fertility of our soil, with a corresponding decline in food production with which to supply our growing population.

Of course, it is not true. Fortunately for all of us, it is scarcely possible for any statement to be more fantastically untrue. What is the source of organic matter? It is vegetation. How does vegetation create organic matter? By absorbing its constituents from the air. Plants manufacture starch, sugar, and cellulose from carbon dioxide and water which they find in the earth's atmosphere. Even the nitrogen in the plant's protein is derived partly from the air and it is a logical assumption that, originally, all of it came from that source. As long, then, as the earth has an atmosphere, the source of organic matter is inexhaustible.

It is also worth remembering that the disposal of great volumes of excess organic matter is one of the biggest problems which face the governing bodies of all towns and cities. Removal of garbage and sewage is a costly and tiresome business. The day when circumstances will compel us to return our waste products to the land is probably far distant, but no thinking man can believe that the human race can, forever, burn up its capital or run it into the ocean. To make up our losses by means of chemical fertilizers or pulverized rocks is on a par with balancing our accounts by robbing the bank in the next town. Nitrate or potash deposits are not inexhaustible; phosphate quarries are not bottomless. The day must come when the bank in the next town is as exhausted of reserves as we are ourselves. We may leave that problem to posterity but let us not lose sight of it altogether; in the meantime, we can assure ourselves that inexhaustible supplies of organic matter are ours for the asking. We know, too, that sewage and garbage, by a simple process, can be made into a completely innocuous and wholesome product of high fertilizing value; in fact, that very thing is being done today in various parts of Europe, in South Africa, and in our own United States of America.

What, then, is the real situation that faces us? We have the organic school advocating the addition of minerals to the soil and we have the chemical school urging, just as strongly, the use of organic matter. Wherein does the conflict lie? That question can be answered in a few words by saying that the chemical school recommends the use of highly soluble chemicals while the organic school advocates fertilizers that are only soluble and are released to the roots of crops by slow and natural processes.

One of the claims made for chemical fertilizers is that their high solubility renders them more available. Let us examine that theory, but first let us realize how fallacious is the commonly held belief that the roots of plants drink up solutions of chemicals which are added to the soil. The exact method by which plants obtain their nutriment is still not fully understood, but all informed persons are agreed that the process is a complex one in which the colloidal constituents of the soil, or its bacteria, or both, probably play important roles. Without dwelling on that aspect of the question, let us consider some of the better known chemical fertilizers.

The nitrogenous fertilizers, nitrate of soda and sulfate of ammonia, are both of high solubility. For either of them to be available, weather conditions must be just right. If their use is followed by heavy rain, they are washed into the subsoil, from there to the rivers and so out to sea—and the farmers' dollars go with them. Obviously, they are not then available. The consequences of a drought can be still more disastrous. H. M. Hofford, discussing this matter in New England Homestead for April 22, 1950, wrote:

> Experiments showed that heavy fertilization only aggravated conditions due to lack of water. With a large amount of fertilizer and not enough moisture, the soil solution became so concentrated that the roots of corn plants are browned and killed by the expensive fertilizer that was put there for the good intention of feeding the plants.

Merely because a fertilizer is soluble, therefore, it by no means follows that it is available. With too much rain, it is washed out of reach; with too little, it burns the roots of the plants it was meant to feed.

When we come to superphosphate, we are presented with a situation so fantastic as to be almost unbelievable. Phosphate rock is treated with sulfuric acid to render it more soluble. Because of its solubility, it reacts readily and quickly with compounds existing in the soil to which it is added. If the soil tends to be alkaline, the superphosphate reacts with any calcium present and reverts right back to the insoluble phosphate from which it was made; if the soil tends to be acid, the superphosphate reacts with iron, or aluminum, or both, and forms compounds which are even less soluble than the phosphate rock.

These facts are well known to all soil scientists and have been for many years. Professors Lyon and Buckman of Cornell in their standard work, The Nature and Properties of Soil (fourth edition, 1943) tell us that when superphosphate is added to a soil containing a large amount of active calcium, it reverts back to compounds which "unfortunately are quite insoluble and rather unavailable to plants." On the other hand, when the soil is acid, the "reversion products are even more insoluble."

Dr. Firman E. Bear, writing in The Land, autumn issue, 1949, said:

> Long ago we learned that of the total amount of phosphorus and of potassium that is applied to a soil, only a small fraction is recovered the first year or even over a considerable period of years. In other words, soils have a tremendous capacity to fix or insolubilize these elements, especially phosphorus.

In New England Homestead for January 27, 1951, William Gilman describes some recent work done by Dr. Dale Seiling, chief of the Massachusetts Experiment Station, and his associates. We are told that they have found that when superphosphate is added to the soil it frequently "just sits there, doing nothing, piling up year after year."

It seems worth while to summarize the strange life story of superphosphate. It starts as phosphate rock which is mined and transported to the factory; there it is treated with sulfuric acid for the sole purpose of making it more soluble. This treatment converts part of it to calcium sulfate which is of no particular value to any farmer in the eastern zone of the country but which acts as a diluent, reducing the phosphate content from around 30 percent to around 18 percent. This diluted phosphate is then shipped to the farmer who, of course, will have to bear the cost of transporting rock from quarry to factory and of treating it with sulfuric acid. He adds the doctored rock to his

soil and quickly gets a compound either equivalent to the original rock or even less soluble. This compound "just sits there, doing nothing, piling up year after year."

So the farmer pays a higher price for a product much poorer in phosphate than the untreated rock and one which compels him to add a contaminating compound which, in many cases, he would rather not have. It seems obvious that the only people who benefit from the manufacture of superphosphate are the manufacturers.

The followers of the organic school protest against such foolishness and advise that a soil which needs phospate should get it in the form of finely pulverized rock from which phosphate will be released, as the crop needs it, through the agency of the organic constituents of the soil.

A statement that has been made repeatedly to your committee is that chemical fertilizers give increased yields. For instance, Dr. Bear has told you that "by their use acre yields can often be doubled and trebled," Dr. Bradfield has reported to you that "it has been conservatively estimated that our supply of food and fiber during the war period was increased between 20 and 25 percent by the use of chemical fertilizers." Every year, the United States Department of Agriculture publishes a volume of agricultural statistics. There is, therefore, no need for estimates, conservative or otherwise. The figures are there for everyone to see. One can study them in vain to find a basis either for Dr. Bear's tripling of yields or for Dr. Bradfield's "conservative" estimate of 20 to 25 percent increase in production, by the use of chemical fertilizers.

I propose to examine some of these figures, but before doing so I would like to discuss some of the many factors which determine the size of a crop and the yields per acre. First of all, there is the weather. Of all factors, weather is the most influential. A farmer can have seed of highest quality, fertile soil, years of experience, skilled help, and up-to-date equipment, but if the weather is against him, he is beaten.

In the 1930's, we had a succession of bad seasons with floods, droughts, late wet springs, early fall frosts—every kind of bad farming weather. It was probably the worst succession of growing seasons in the history of American agriculture. Production slumped, yields dropped. In the 1940's the pendulum swung the other way and year after year we had good growing weather. Farm Journal, in its June 1950 issue, referred to this period as "the string of good-weather years that extended straight through the war and 4 years more." To compare production in the 1940's with that in the 1930's leaving weather out of the picture, would plainly be meaningless and misleading. To learn what effect the great increase in the use of chemical fertilizers has had, we must find a period of similar weather conditions when fertilizers were used in relatively small quantities.

Because of the exceptional conditions in the 1940's this has not been easy, but after going over the records in the office of the United States Weather Bureau at the top of the Whitehall Building in New York City, I found that the 6 years 1920–25 compared reasonably well with 1940–45, although the later period still had the advantage because the year 1924 was an exceptionally bad one and pulled down the figures for the whole period.

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Taking our largest cereal crop, corn, I found that production in the 6 years 1920–25 was 16,603,000,000 bushels. In the years 1940 to 1945, production was 17,407,000,000 bushels, an increase of less than 5 percent. Between these two periods, our population had risen from about 110 million, to about 140 million, so our production per head of the population, for the 6-year period, had dropped from 150 bushels to 124 bushels.

Such figures certainly do not bear out the claims for chemical fertilizers quoted above. To be fair, however, we should also consider the yields per acre as well as the total production. When we do so, we make a rather surprising discovery. Although the population between the two periods increased over 25 percent, the acreage of corn dropped approximately 11 percent. Based on this figure, the yield of corn per acre rose 17½ percent. Perhaps it is here that we find the use of chemical fertilizers justified. Let us see. Eleven million acres had gone out of production. It is certain that these abandoned acres were not the most fertile, because labor was scarce and expensive. It did not pay the farmer to use his submarginal land. This elimination of the acres giving lower yields would, of course, bring about an arithmetical rise in the average yield.

Also, between 1920 and 1940 much happened in agriculture. The Department of Agriculture and the Soil Conservation Service had worked ceaselessly at improving farm practices by initiating contour plowing, strip cropping, irrigation, better drainage, and so forth; but, most important of all, corn acreage is planted with hybrids. Richard Crabb, in his book The Hybrid Corn Makers claims for the new corn an increased yield per acre of 36 percent; Q. F. Callender of the Bureau of Agricultural Economics, puts the figure at 21 percent; Dr. Wheeler McMillen, editor of Farm Journal, puts it at 30 percent. Yet, with improved farm practices, and the abandonment of submarginal lands to help hybrid corn, the increase in yields reached a figure of only 17½ percent. In the face of such facts as these, how can anyone claim that, over the years, and taking the country as a whole, chemical fertilizers have increased yields by as much as a bushel?

I do not wish to weary your committee by quoting detailed figures on other crops. Let me merely say that with oats the situation is rather worse than with corn while with wheat it is rather better; but from any one of them or from all of them put together it is impossible to obtain any justification for the high claims made for chemical fertilizers.

As for truck farming, the situation is dismal indeed. In the growing of vegetables, especially in the Eastern States, chemical fertilizers have been freely used for many years, yet the yields per acre for beans, cantaloup, cucumbers, spinach, and tomatoes have, in the last 30 years, dropped by amounts ranging from 15 percent for tomatoes to 40 percent for spinach.

On experimental plots and for a single year spectacular increases can sometimes be obtained; but on a large scale and over long periods of time the story is very different. The key to high production and high yields still remains what it has been through the centuries—organic matter supplemented with such rock mineral as may be required. That statement is well borne out by experiments made at the University of Illinois and reported by Dr. A. L. Lang in an article

published in Better Crops with Plant Food in November 1945. Dr. Lang gave figures showing yields obtained in seven experimental fields which were fertilized only with manure, limestone, and rock phosphate over a 4-year period, 1940–43. The average yield was 104 bushels per acre compared with the average for the whole United States of 32 bushels per acre. The crop was corn.

My final point I introduce with reluctance. I do so only because I believe it goes to the very heart of the matter your Committee is investigating.

I have, upon my desk, an advertisement published by the National Fertilizer Association. I think it is fair to call it a typical advertisement. It contains much truth, as all advertisements must if they are to carry conviction. It contains many half-truths and some which barely reach the halfway mark. From beginning to end it is extremely biased—again, a necessary characteristic of advertising matter. Its by-line reveals that it was written by a distinguished professor on the staff of one of our more important agricultural colleges. On the front page is an excellent portrait of the author with a caption setting forth some of his achievements and the positions he has held.

Everybody knows that such things are done and nobody seems to care; but what should we think of a distinguished physician, perhaps the head of one of our famous hospitals, if he wrote an advertisement for a proprietary medicine and not only allowed his name to appear but permitted his portrait to be printed on the front page? How long would he retain his professional standing? How long would he remain a member of the American Medical Association?

If it is undignified and unethical for a distinguished physician to write advertisements for one commercial product, why is it not equally undignified and unethical for a distinguished agronomist to do the same thing for another commercial product? If some of the professors in our agricultural colleges are employees of the National Fertilizer Association or of any of its members, can we be quite confident that their teaching is entirely unbiased? If some of the members of the staffs of our State experiment stations are receiving compensation in any form from the same source, can we be fully satisfied that all their research work is wholly in the interests of the farmers and to no slightest degree in the interests of manufacturers of fertilizers, poison sprays, or other materials or equipment used in agriculture?

Upon your shoulders, gentlemen, rests a share of the heavy burden of making our country's laws. I respectfully suggest to you that legislation should be introduced making it illegal for any person who receives compensation, in any form, from a source connected with the manufacture or sale of material or equipment used in agriculture, to hold, at the same time, any position on the staff of an agricultural college or of a State experiment station.

Mr. KLEINFELD. Is it your position, Mr. Wickenden, that we should not use chemical fertilizers at all?

Mr. WICKENDEN. That is my belief—they should not be used at all.

Mr. KLEINFELD. As a practical matter, do you think that the many thousands of farmers could get along without the use of some chemical fertilizer?

Mr. WICKENDEN. I am quite sure they could, because it is being done today.

Mr. KLEINFELD. Where would they get the organic type of fertilizer in sufficient quantity so that, as a practical matter, they could produce crops?

Mr. WICKENDEN. On a large farm, Mr. Kleinfeld, it must be done to a large extent on the farm itself. There must be a rotation of crops, one crop, of course, being largely leguminous, so as to get a fixation of nitrogen in the soil, and then you must switch over in some part of your rotation to grazing. I don't think the problem can ever be solved as long as we have monoculture. It is fundamentally unsound agriculture to grow one crop on a piece of land year after year. If you switch over to grazing somewhere in your rotation, animal droppings provide the animal matter and by growing cover crops and plowing them under you get vegetable matter. That is the procedure which is followed in well-run organic farms today.

Mr. KLEINFELD. It would be necessary for a farmer to diversify his crops?

Mr. WICKENDEN. Absolutely. I think that must come sooner or later.

Mr. KLEINFELD. And I think you mentioned—I don't know whether you are advocating it—the use of sludge or garbage for organic fertilizers.

Mr. WICKENDEN. I don't think I actually advocated it. I think I said it was a possibility for the future. Not only a possibility, I think again it will be necessary in the long run, because today we are taking our minerals from the soil running them into the ocean or wasting them.

Mr. KLEINFELD. There you would meet problems, I suppose, of expense and sanitation; would you not?

Mr. WICKENDEN. Of course, it is very difficult to say offhand, but I doubt very much, if the expense would be any greater than the expense of chemical fertilizers. Then as far as sanitation is concerned, I am one of the people who can't see that what we are doing today is a very sanitary procedure. It doesn't matter what city I visit, I ask for a glass of ice water and I am given a chlorine highball.

What we do today is to take our sewage and run it into the lakes, rivers, and the ocean, and then we drink the water out of the lakes and rivers, and we swim in the ocean. That doesn't seem to me sanitary or very advanced hygiene.

Mr. KLEINFELD. Mr. Wickenden, if a farmer uses some sort of pulverized rock or pulverized rock material as a fertilizer, would you call that organic or inorganic?

Mr. WICKENDEN. The rocks, of course, are inorganic. This word "organic" has been applied to this particular method of agriculture, but all of us who follow the organic method, as I said in my statement, use a number of inorganic rocks, such as limestone, phosphate rock, potash rock, and so forth.

Mr. KLEINFELD. You wouldn't exclude them; would you?

Mr. WICKENDEN. Certainly not. I would definitely advocate their use.

Mr. KLEINFELD. Although they are inorganic in nature?

Mr. WICKENDEN. Yes.

Mr. KLEINFELD. But outside of the rock type of material you would exclude all inorganic fertilizers?

Mr. WICKENDEN. All soluble artificially made chemicals; yes.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. This new product that we read so much about, which is put out by a St. Louis concern, I believe within the last 2 weeks——

Mr. WICKENDEN. Yes.

The CHAIRMAN. That is not an organic material, it adds nothing to the soil; is that right?

Mr. WICKENDEN. Well, it is an organic material, but it is entirely unaffected by the bacteria in the soil. From what I have read in the papers it remains there forever. It is not broken down by bacteria. It is apparently a material to improve the texture of the soil.

The CHAIRMAN. It is designed particularly for that clay soil along the Atlantic coast; is that right?

Mr. WICKENDEN. That might be. I wouldn't know. I say, I know very little about it; as I understand, what it does is to improve the texture of the soil. It is not a fertilizer.

The CHAIRMAN. Don't we have sludge sold commercially? Don't many cities reclaim their waste material and have sludge plants?

Mr. WICKENDEN. Yes.

The CHAIRMAN. And that is sold commercially today; is that right?

Mr. WICKENDEN. That is right; Milwaukee turns out a product called milorganite, which is sold by the bag.

The CHAIRMAN. And that has value?

Mr. WICKENDEN. Yes; it has value. I have used it myself on my own place.

Mr. ABERNETHY. How do you spell that?

Mr. WICKENDEN. M-i-l-o-r-g-a-n-i-t-e.

Mr. ABERNETHY. I have used that material, too.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. Your testimony is very interesting. I come from a farming area where my farmers have used a considerable portion of chemical fertilizers.

Now, as I understand your statement, Mr. Wickenden, the thing that you point to is more or less an economic problem. It is your opinion that the money which the farmers are spending today for chemical fertilizers is resulting in a complete loss to them.

Mr. WICKENDEN. I think in the long run it is bound to do so.

Mr. ABERNETHY. Well, now, you are not modifying your statement, are you, when you say "in the long run"?

Mr. WICKENDEN. I said, I think, in my statement "over the years." And that the increase in yield brought about by chemical fertilizers disappeared over the years. Temporarily you get an increase.

Mr. ABERNETHY. The point you make is, as I understand you—and I want to get this clear—that the use of chemical fertilizers in the long run does not improve the economic status of the farmer.

Mr. WICKENDEN. I think that is perfectly true, because it doesn't improve his soil in the long run.

Mr. ABERNETHY. It doesn't improve production of his crops.

Mr. WICKENDEN. That is right.

Mr. ABERNETHY. I have visited numbers and numbers of experiment stations where chemical fertilizers in different mixtures—we will say in 10, 6, 4, and 4, 8, 12—you understand what that means?

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. That is the proportion of nitrogen, potash, and phosphate, and so forth.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. Where they have used chemical fertilizers in different quantities and on certain crops over a period of a number of years, and these crops will be produced on identical soil, the same crop—an experiment plot here and next to it another experiment plot and next to that another, and so on.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. And the yield in some of the plots would far exceed the yield in the others, all under the same weather conditions year in and year out.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. How do you account for that? In other words, in these stations it was definitely proven that the yields were improved where the chemicals were used as against those where no chemicals were used, growing side by side.

Mr. WICKENDEN. I think that is quite possible, Mr. Abernethy; but did they have another plot to compare with these chemical plots in which nothing had been used but organic matter and pulverized rocks?

Mr. ABERNETHY. That is not my point. You make the point that the use of the organic matter now might be better than the inorganic.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. I am not making that point. I am saying we take a tract of ground, let's say 5 acres, and on all 5 acres we plant the same crops, the same seed produced from the same particular source.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. And the first acre, they plant that seed and later fertilize it with a certain type of fertilizer.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. In the next acre they plant the same seed and fertilize that with a certain type of chemical fertilizer. The next acre has another type, and the next would have no fertilizer at all.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. And these experiments prove out, Mr. Wickenden. The first acre, let us say, its production would be X, and the next acre would be Y or less, and the next acre Z even less, and in the acre where no fertilizer at all was used, there would be the lowest production.

Mr. WICKENDEN. Yes.

Mr. ABERNETHY. I am giving you some factual illustrations. Now how do you account for that? I am not disputing your statement; I am asking you how you reconcile those experiments with your statement.

Mr. WICKENDEN. I reconcile them with the statement by the wording I used in my statement—that for a time chemical fertilizers will increase yield, but you are doing it at the expense of the organic matter in the soil.

Mr. ABERNETHY. You didn't say in your statement that it was destroying the inorganic matter.

Mr. WICKENDEN. Destroying the organic matter.

Mr. ABERNETHY. Did you make the statement——

Mr. WICKENDEN. I don't think I made the statement that——

Mr. ABERNETHY. Did you make the statement "destroying the organic matter with the use of chemicals"?

Mr. WICKENDEN. I don't say destroying it. This is what I think happens, if I may go into this a little more in detail.

When you add a chemical fertilizer to the soil, I think the first thing that happens is a great increase in the bacterial content of the soil. Now the normal way by which all crops obtain their nourishment is from the breakdown of the humus in the soil by the bacteria in the soil. If you get a great increase in the number of bacteria, you get an increase in the rate of breakdown of the organic matter or the humus, as it is called, and that is what brings about the increase in the yield of the crop.

As I recall, when Dr. Albrecht, I think it was, was giving evidence to your committee——

Mr. ABERNETHY. Yes.

Mr. WICKENDEN. He made some remark—I can't repeat it verbatim, but something to this effect: that when you add chemical fertilizers to your soil, some people say you are destroying the soil; you are not destroying the soil at all, what you are doing is using it up more quickly; and I think that is true. Have I made myself clear now?

Mr. ABERNETHY. I don't know whether you have or not. I can't reconcile your statement with what you have said now.

As I understood your statement, you left a definite impression that the addition of chemical fertilizers would not increase the yield, and I firmly believe, Mr. Wickenden—I may be absolutely mistaken, but this is my firm conviction about it—I believe if you were to withdraw all chemical fertilizers from the market today, there would be a famine in this country in a few years' time. I honestly believe that.

Mr. WICKENDEN. We got ourselves into a mess, Mr. Abernethy.

Mr. ABERNETHY. Maybe we have.

Mr. WICKENDEN. You can't get out of a mess in 10 minutes. It might take us many years to get back to a reasonable, sound scientific form of agriculture. But I don't advocate passing a law stopping the sale of all chemical fertilizers tomorrow.

Mr. ABERNETHY. I am not taking the position that either the chemical or organic is better than the other in this discussion. I am not taking a position on that at the present time. I may have an opinion about it. I don't take the position one is better than the other, but I do take the position that the use of chemicals does increase the yield of the crop.

Mr. WICKENDEN. I think it does temporarily. May I read this from my statement?

Mr. ABERNETHY. Certainly.

Mr. WICKENDEN. On experimental plots and for a single year spectacular increases can sometimes be obtained, but on a large scale and over long periods of time the story is very different.

Mr. ABERNETHY. Well, how long?

Mr. WICKENDEN. We will take some of the experiments at Rothamsted. They ran an experiment—you always hear about the wheat, but you never hear about the barley there. They ran a test there, as I remember, for a period of 70 years, and they made——

The CHAIRMAN. How many years?

Mr. WICKENDEN. Seventy.

The CHAIRMAN. Seven ought?

Mr. WICKENDEN. Yes, 70 years.

They made a direct comparison between farm manure and chemical fertilizers. I am speaking from memory, so the figures may not be exactly accurate. It was something like this: for the first 20 years the chemical fertilizers were winning out, but subsequently the yields from the chemical fertilizers, those plots, began to go down and down. At the end of 70 years the yields were so bad they stopped the experiment. The plot that had been treated with farm manure, farm manure only, mind you, without any phosphate rock or anything else, just farm manure, the yields from that plot were still holding up very satisfactorily, and in the last 30 years of the test the yields from the plot treated with farm manure was 30 percent higher than that from the chemically treated plots.

Mr. ABERNETHY. I would like to call attention to one other thing, Mr. Chairman, and then I am through. I am sorry I have prolonged this discussion so much.

Mr. Wickenden, in the last paragraph of your statement, you have referred to something which, if true, is rather alarming. Now I want to get this on the record clearly.

Do you make the charge that an appreciable number of people holding positions with the agricultural colleges of the country and the agricultural stations are aiso on the payrolls of the chemical manufacturers?

Mr. WICKENDEN. I know that some of them are. How many, of course, a private citizen is in no position to find out. But what I suggest is that the temptation to do such a thing should be removed by making it——

Mr. ABERNETHY. Of course, that would have to be done by the State legislatures who supervise the agricultural colleges. After all, most of them are State institutions. None of them are Federal institutions, they are State institutions.

Mr. WICKENDEN. I am not a legislator, so I do not know the details of the procedure, but I certainly think it is something that should receive a great deal of attention.

Dr. HEDRICK. How long have chemical fertilizers been used in this country?

Mr. WICKENDEN. How much?

Dr. HEDRICK. How long?

Mr. WICKENDEN. I think it goes back in a very small way, probably 40 years, but they did not really come into very great use until the late 1930's or early 1940's. There has been a very big increase in the last 10 or 12 years.

Dr. HEDRICK. What is the cause of that increase?

Mr. WICKENDEN. Well, I suppose it is good salesmanship.

Dr. HEDRICK. Do you think the American people are so easily fooled that they would fall for something over a period of 20 years?

Mr. WICKENDEN. I don't say they are easily fooled. When you have so many of the agricultural colleges preaching chemical fertilizers, Dr. Hedrick, how can you say the farmers are easily fooled, when they are under such tremendous pressure. The farmer is taught the use of

chemical fertilizers by the experiment stations, by the agricultural colleges. Almost all the big ones are preaching chemical fertilizers.

Dr. HEDRICK. You take a poor old farmer out in the country who does not know anything about the theories taught in colleges, all he knows about is plowing the soil and what he raises. I know farmers who have doubled crops by the use of chemical fertilizers.

Mr. WICKENDEN. It is possible, because they may have let the soil run down. But you must always make a comparison between chemical fertilizer and a properly fed soil which has been kept in good shape by use of organic matter and possibly pulverized rocks and so forth.

Dr. HEDRICK. That is all.

The CHAIRMAN. Mr. McDonough.

Mr. MCDONOUGH. Doctor, do you think lime and phosphate are essential to soil in bringing about an increased production of the crop?

Mr. WICKENDEN. Well, I know that lime is very helpful. I know that on my own land, which I brought 7 years ago, it has been very helpful, because the soil when I went there was extremely acid, and when we tested it, we found it had a very low pH. I feel sure I couldn't have brought it to the present state of high fertility without the use of ground limestone.

Mr. MCDONOUGH. In other words, the reason I ask that, the so-called chemical fertilizers, which you call inorganic, and organic fertilizers, which are always, we have to admit, both chemical——

Mr. WICKENDEN. Yes.

Mr. MCDONOUGH. In the organic field we don't get much lime and phosphate, we get mostly nitrogen and stimulation of the humus of the soil through the other materials that may be used, in the droppings of the animal and vegetation.

Mr. WICKENDEN. Yes, sir.

Mr. MCDONOUGH. Of course, the organic development, the feeding of the soil with an organic compound is a slower process than the stimulation of the soil with the chemical soluble lime and phosphate. Is that not true?

Mr. WICKENDEN. I think it is true to a limited extent, yes.

Mr. MCDONOUGH. As I gather from what you say, over the long run the lime and phosphate, the so-called chemical fertilizers which are soluble, and given good weather conditions, where they get into the plant food and are not absorbed in the soil and burn the root up, they will eventually rob the soil of many of the organic chemicals that should be retained and would be retained if you used an organic fertilizer?

Mr. WICKENDEN. That is right.

Mr. MCDONOUGH. Now, of course, that is all very interesting economically from an agricultural point of view, and I appreciate the interest Mr. Abernethy and Mr. Jones and Dr. Hedrick have shown. The purpose of this committee was to find out if in the use of any fertilizer, organic or inorganic, the material used in the production of the plant life and the food would eventually get into the human system in some poisonous form. Do you have any testimony along those lines?

Mr. WICKENDEN. Absolutely none.

Mr. MCDONOUGH. Do you have any belief—well, we will ask the question this way: Do you think the chemical fertilizers, which include the lime and phosphate and some soluble nitrogenous com-

pounds, that the use of those would possibly bring about some poisonous conditions in the plant food quicker than the use of vegetation?

Mr. WICKENDEN. May I say this in reply—the only suggestion I ever heard that chemical fertilizers produce anything poisonous in the crop is the one that was brought before your committee, in which it was suggested that excessive nitrates in the soil might result in excessive nitrates in the crop, and that those excessive nitrates would break down in the human body and cause damage.

Mr. MCDONOUGH. That is known to occur in animal life.

Mr. WICKENDEN. That is the only case I have ever heard of. And with regard to superphosphate or muriate of potash, or any of those fertilizers, it is quite inconceivable to me they could result in anything poisonous in the crop.

May I go just a little further? I think it has been conclusively demonstrated that crops grown with organic fertilizers contain health-giving ingredients which crops grown with chemical fertilizers do not contain, and on that point I am quite convinced. There is so much all through the scientific literature to prove it, that I don't see how there can be much argument.

Mr. ABERNETHY. Will the gentleman yield?

Mr. MCDONOUGH. Yes.

Mr. ABERNETHY. Is that an opinion, or have you made some experiments to prove it?

Mr. WICKENDEN. I can keep you here all afternoon——

Mr. ABERNETHY. You have made some experiments?

Mr. WICKENDEN. Let's go back——

Mr. ABERNETHY. I wouldn't ask you to——

Mr. MCDONOUGH. Answer "Yes" or "No." Have you made experiments?

Mr. WICKENDEN. Oh, no; I am not a medical man.

Mr. MCDONOUGH. Have you made experiments in the production of vegetables and food from the soil with organic fertilizers that you know are more healthful and more nutritious than the plant life produced by chemical fertilizers?

Mr. WICKENDEN. No; I am bound to say "No" to that.

Mr. MCDONOUGH. In other words, you are theorizing?

Mr. WICKENDEN. No, I am not theorizing. I can quote you the experiments that have been made by much more competent persons than I am in that field, by doctors and dietitians and so forth.

Mr. MCDONOUGH. Let me ask you this: Is the possibility of the loss of a crop from the use of chemical fertilizers more potential than the possibility of loss of a crop through vegetation and organic fertilizers?

Mr. WICKENDEN. The loss of a crop?

Mr. MCDONOUGH. Yes.

Mr. WICKENDEN. Yes, I think you have a much safer crop if you have a soil which is rich in organic matter than if you rely on inorganic chemical fertilizers.

There are two reasons for that: First, with chemical fertilizers, the roots tend to stay nearer the surface because that is where the food is. The crop is then less resistent to drought. The other reason is it has been found repeatedly that crops fed with chemical fertilizers tend to lodge—I mean they fall down in bad weather more than crops grown with organic fertilizers.

Mr. McDONOUGH. Thank you very much. That is all.
The CHAIRMAN. Anything further?
Mr. KLEINFELD. Nothing further.
The CHAIRMAN. Thank you very much.
Mr. WICKENDEN. Thank you.
The CHAIRMAN. Call your next witness.
Mr. KLEINFELD. Mr. Levin.
The CHAIRMAN. Your name and address?
Mr. LEVIN. Franklin Levin, 1432 North Randolph Street, Philadelphia.
(The oath was administered by the chairman.)
The CHAIRMAN. You may proceed.

TESTIMONY OF FRANKLIN LEVIN, PRESIDENT, CURLEY CO., INC., PHILADELPHIA, PA.

Mr. KLEINFELD. Mr. Levin, you are president of the Curley Co.?
Mr. LEVIN. Yes.
Mr. KLEINFELD. What are your duties?
Mr. LEVIN. Management of the company.
Mr. KLEINFELD. Do you have any scientific or technical background?
Mr. LEVIN. I had four technical courses in chemistry at Temple University.
Mr. KLEINFELD. And did you receive a degree from Temple?
Mr. LEVIN. No.
Mr. KLEINFELD. That is the extent of your technical experience?
Mr. LEVIN. Yes.
Mr. KLEINFELD. Please read your statement.
Mr. LEVIN. The telegram of December 7, 1951, from Hon. James J. Delaney, chairman of the House Select Committee To Investigate the Use of Chemicals in Food Products, has been received and acknowledged as requested.

The Curley Co., Inc., will be represented at the hearing scheduled for 10 a. m. on January 10, 1952, in New York City, by Franklin Levin, president of the corporation.

The Curley Co., Inc., currently manufactures the following cosmetic products: dandruff-treatment shampoo; lather-oil shampoo; cream with egg shampoo; latherless-oil shampoo; concentrated cream shampoo; concentrated lather oil shampoo; permanent-wave lotion, machine type; permanent-wave lotion, cold-wave type; cuticle remover; nail-polish remover; all-purpose cream, cold-cream type; hand lotion; hair cream oil; hair lacquer; after-shave lotion; brushless shave cream; lather shave cream; concentrated shave cream for latherizing machine; talcum powder; bubble bath; and liquid deodorant.

The ingredients contained——

Mr. KLEINFELD. Mr. Chairman, I suggest he skip the names and they be put in the record as though read.

The CHAIRMAN. Very well.

Mr. LEVIN. The ingredients contained in the foregoing products are:

(A list of the ingredients is in the files of the committee.)

Curley Co., Inc., before manufacturing for distribution a new cosmetic product, follows this procedure:

The laboratory checks the literature, the suppliers of raw materials, and competitive products. With this information at hand, series of samples are formulated and checked for various chemical and physical properties. After one of these formulations is acceptable to the laboratory, the product is used by the personnel and people in close association with the company. If this test proves satisfactory, the company then distributes the new product to a limited sampling of beauty shops, and more individuals. If this stage of the test is satisfactory, the product is then distributed to a jobber for sale in a local area. If these reports are satisfactory, the company is prepared to distribute the new product on a general basis.

Curley Co., Inc., has for many years maintained a control laboratory which is used to insure that each batch of product conforms to the established chemical and physical standards. No laboratory animals have been used but limited patch testing has been done on humans.

Recently, when the Curley Co., Inc., made some changes in its dandruff-treatment shampoo, the new product was tested in the eyes of animals, in accordance with Food and Drug Administration methods. The testing on the animals was conducted in the Curley Co. laboratory. The results, together with the formulation, were submitted to the Food and Drug Administration, who found no objections. An independently operated toxicology laboratory confirmed these tests.

Curley Co., Inc., is organizing a system for studying all of its cosmetic products for toxicity. Tests on some of the products have already been started.

This company is very much in favor of the investigation and study of the use of chemicals in the cosmetic industry. It is willing to cooperate with the committee to the best of its ability.

Perhaps cosmetic manufacturers should be licensed or registered, so that the Food and Drug Administration could communicate with them directly, making available to them standards, methods of tests, changes, listings of unsafe chemicals, et cetera, or other pertinent information that might develop. This would appear to be preferable to the present indirect methods of obtaining information from publications, trade associations, or from Government agencies by specific inquiry.

It is thought that it would be most helpful, both to the manufacturers of cosmetics and to the public generally, if the Food and Drug Administration established specific tests for particular classifications of products. For instance, if there is a reasonable danger that a particular cosmetic might affect a part of the body for which it is not intended, but which might be contacted during conditions of use as are customary and usual, the Food and Drug Administration should specify that the cosmetic in question be tested for toxicity, to that specific part of the body, or by a specific test which would eliminate any doubt.

It is suggested that standard formulas be established for cosmetics. For instance, a range of percentages and ingredients contained in a product could be set forth. Then, if a manufacturer complied with the established standards, no further elaborate pretesting would be necessary. This would be economical for the Government, the manufacturer, and the public. It would also keep regulatory details to a minimum. Products not falling within a standard formula should be

pretested for toxicity. Standard methods of testing should be devised and published in order to eliminate the possibility of future discrepancies; the results of the tests conducted by the Food and Drug Administration prior to marketing, or during routine inspections. These tests are very costly at present. This new volume of work based on production should reduce the cost and bring it within the scope of small companies.

Perhaps it would be helpful to include within the regulations chemical ingredients which are sold to manufacturers for use in cosmetics. If the burden of establishing toxicological data is on the producer of basic materials, this would be of general economic value, since among other advantages, the ingredients would be tested at the source instead of by the many manufacturers of cosmetics. In addition, it should be required that the supplier of raw materials change his product name or number when any changes in the raw materials are made. Products supported by laboratory data should not be offered on a nonwarranty basis, but should be guaranteed as represented. It is not suggested that a manufacturer be required to test a chemical for use in a cosmetic when such a chemical is not intended for this purpose. If a cosmetic producer desires to use such a chemical, the burden should be upon him to do the necessary testing of the raw material as well as of his finished product.

If any additional information is required, this company will be glad to furnish it.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Mr. Levin, are the products which you list in your statement all the products which you now make or have made in the recent past?

Mr. LEVIN. Within the last year, anyway.

Mr. KLEINFELD. And does the list of ingredients which you have furnished this committee contain all the ingredients which you now use or have used in the recent past?

Mr. LEVIN. I noticed one omission and one correction.

Mr. KLEINFELD. What is that?

Mr. LEVIN. Polyethylene, ester of mixed fatty acids and resin acid is one. Potassium bromate is another.

We described one of the products with the omission of the aryl radical. It is alkyl aryl polyethylene oxide, which we described as alkyl polyethylene oxide.

Mr. KLEINFELD. Does that complete the list?

Mr. LEVIN. So far as I know.

Mr. KLEINFELD. Do you submit your cosmetics to the cosmetics committee of the American Medical Association for acceptance?

Mr. LEVIN. No; we do not.

Mr. KLEINFELD. On page 2 of your statement, you say your company has for many years maintained a control laboratory which is used to insure that each batch of product conforms to the established chemical and physical standards. You say, "no laboratory animals have been used, but limited patch testing has been done on humans."

What kind of personnel do you have in this laboratory?

Mr. LEVIN. There is a chemist who has been in the industry for quite a number of years. His name is Ben Levitt. His background goes back probably to 1910, when he attended Columbia—no, I believe it was City College of New York, as a special chemistry student. He

has written more than 50 technical articles and recently had a book published.

Mr. KLEINFELD. Anybody else?

Mr. LEVIN. On a full-time basis, that is all.

Mr. MCDONOUGH. You mean he is the man who does the testing, he is the person who tests the product before it is released to the public? Is that the question?

Mr. LEVIN. That was the chemical testing.

Mr. KLEINFELD. What other testing do you do?

Mr. LEVIN. The other testing is that we use——

Mr. KLEINFELD. Who is "we"?

Mr. LEVIN. Well, Mr. Levitt, myself, my brother, my family employees in the factory.

Mr. KLEINFELD. How many altogether?

Mr. LEVIN. Well, it usually starts off with a half a dozen, and then another half a dozen or a dozen, and that is the initial stage.

Mr. KLEINFELD. About a dozen?

Mr. LEVIN. At least a dozen before we send it out to beauty shops, which we have to test our materials.

Mr. KLEINFELD. What kind of tests are performed on these dozen persons?

Mr. LEVIN. They are primarily use tests. If it is a shampoo, it is put on and rinsed according to the directions.

Mr. KLEINFELD. Who checks the results which you obtain?

Mr. LEVIN. Either I do, or Mr. Levitt, or it is usually a combination.

Mr. KLEINFELD. Mr. Levitt is a chemist, and you have no training, have you, in the scientific field?

Mr. LEVIN. As I mentioned, I had technical courses at Temple but did not include any degree work.

Mr. KLEINFELD. Do you employ the services of a dermatologist?

Mr. LEVIN. No.

Mr. KLEINFELD. So your patch tests are conducted on about 12 people; is that right?

Mr. LEVIN. Yes. On the patch testing, when we have run those we have a physician who has checked these people.

Mr. KLEINFELD. What do you do with your shampoos in the way of testing?

Mr. LEVIN. Well, it has just been on regular use tests. It has been tested on individuals for use, and then to beauty parlors on a limited scale.

Mr. KLEINFELD. Do you put drops of the shampoo in the eyes of these 12 persons?

Mr. LEVIN. No; but at present we put the shampoo in the eyes of rabbits, after some recent discussions with the Food and Drug Administration. We were just advised of the particulars which are used specifically for determining the safety of shampoos in the eyes.

Mr. KLEINFELD. Just advised, you say. Did you ask them for advice?

Mr. LEVIN. No. At the end of August we were notified by the department that they had some complaint on the product, and we had heard that a shipment made to a customer had been seized, and we were to discuss the product with them in Washington.

Mr. KLEINFELD. When was this?

Mr. LEVIN. The end of August.

Mr. KLEINFELD. What year?

Mr. LEVIN. 1951.

Mr. KLEINFELD. Did you receive any complaints from any consumers prior to that time?

Mr. LEVIN. We had received three complaints. One was in February, another was approximately April, and there was a third one in June. And on these complaints we were notified that the product had gotten into the person's eye. And in one case the doctor had asked what was in the material and we wrote him about it and gave him the information. When we checked with him later, he determined that some of the material had gotten into this woman's eye and she had not rinsed it sufficiently, and he had irrigated it and that it was all right.

Mr. KLEINFELD. What was the nature of the complaints received from these three persons?

Mr. LEVIN. That the product had gotten into the eye.

Mr. KLEINFELD. And had caused what?

Mr. LEVIN. An irritation and a burn.

Mr. KLEINFELD. What did you do when you got these complaints—did you recall your product?

Mr. LEVIN. No; we didn't recall the product until later in the year, but what we did at the time was to turn the complaints over to the insurance company, who followed them up, and they discharged them as no injuries, that they were just normal complaints.

Mr. KLEINFELD. What do you mean by normal complaints?

Mr. LEVIN. Well, they were just irritations, there was no absolute injury or damage to the eye.

Mr. MCDONOUGH. Will the counsel yield?

Mr. KLEINFELD. Yes.

Mr. MCDONOUGH. What was the material that you found was irritating to the eye that was in your product?

Mr. LEVIN. According to the tests that we have been doing in the last few months, we found it is the alkyl aryl polyethylene derivative. In the concentration we were using it, it was in excess of the quantity which was to be tolerated by the eye in accordance with the methods that are used by the Food and Drug Administration.

Mr. MCDONOUGH. Is this a product that is under a brand name, or is this a bulk material that is delivered to beauty shops for their use?

Mr. LEVIN. The material was sold to the beauty parlors.

Mr. MCDONOUGH. As bulk material?

Mr. LEVIN. In gallons and quarts.

Mr. MCDONOUGH. It is not something you can go in the drug stores and buy in small quantities?

Mr. LEVIN. It is not sold over the counter. However, we did pack in 8-ounce bottles prior to the recall.

Mr. MCDONOUGH. This particular chemical you found was irritating to the eye, why was it added to the shampoo at all?

Mr. LEVIN. It was an ingredient that was thought to be one that would make a good ingredient as far as the shampoo, and the purpose of the product was concerned, and when it was formulated it had not occurred to us that the product could be tested in the eyes of laboratory animals.

Mr. MCDONOUGH. Is it an acid base?

Mr. LEVIN. It is a combination of polyethylene oxide.

Mr. MCDONOUGH. It is organic?

Mr. LEVIN. It is an organic compound?

Mr. MCDONOUGH. A synthetic compound?

Mr. LEVIN. Yes.

Mr. MCDONOUGH. And since you found it was irritating to the eye, even in spite of the fact your insurance company reported it was not serious damage, what did you do about the quantity you put in future batches?

Mr. LEVIN. Well, we recalled the material that was on the street, and we tested new formulations in the laboratory in the eyes of animals according to the standards that were set forth in this test, and after we had a product that we thought was satisfactory for the purpose, as well as satisfactory for nonirritation, we took the results to the Food and Drug Administration, discussed the formulation with them, showed them the results of the tests we had been running on the animals, and they seemed satisfied that it would be all right to remarket the product. We at the same time had the tests confirmed by an independent toxicologist.

Mr. MCDONOUGH. That is the case you referred to in your testimony here on page 2—that is, page 2 of your letter to Mr. Kleinfeld?

Mr. LEVIN. Yes.

Mr. MCDONOUGH. I am reading page 2, the last paragraph.

Mr. LEVIN. Yes.

Mr. MCDONOUGH. You stated:

> The new product was tested in the eyes of animals, in accordance with Food and Drug Administration methods. The testing on the animals was conducted in the Curley Co. laboratory. The results, together with the formulation, were submitted to the Food and Drug Administration, who found no objection. An independently operating toxicology laboratory confirmed these tests.

As a businessman now, don't you think it would be very wise for you to have a toxicologist or a dermatologist check your own chemical laboratory and your formulas before you get any complaints on your product?

Mr. LEVIN. We certainly do. And while we were even running these tests ourselves on the revised formulation, we had a doctor in reviewing the tests and working along with us on them. We now have plans to have all of our cosmetic products tested according to the various methods.

Mr. MCDONOUGH. And you think the cosmetic manufacturers ought to be registered with the Food and Drug Administration and any new product reported to them before it is used?

Mr. LEVIN. Yes, I do; and I feel there should be a direct flow of information from the Food and Drug Administration to the manufacturers, so that as soon as they get any word that any product or ingredient might not be safe, that information could be immediately sent to various manufacturers, and anyone using those ingredients could automatically check into it.

Mr. MCDONOUGH. Don't the cosmetic people have a research laboratory that they all belong to, and which runs tests, like some of the manufacturers in food products? Isn't there any such institution?

Mr. LEVIN. I do not know of it.

Mr. KLEINFELD. This is a good point to recess until after lunch, and I will ask Mr. Levin to come back.

The CHAIRMAN. We will recess until 1:45 or as close to it as we can.

(A recess was taken at 12:40 p. m., until 1:45 p. m.)

AFTERNOON SESSION

The CHAIRMAN. Let the committee be in order.

Mr. Levin is recalled.

TESTIMONY OF FRANKLIN LEVIN—Resumed

Mr. KLEINFELD. Mr. Levin, I would like to read to you a report made to this committee by the Food and Drug Administration concerning two shampoos which were on the market during 1951, and after I finish reading, I will ask you whether one of the shampoo products was yours.

Here is what the Food and Drug Administration told this committee:

> During the month of August 1951 the product of two shampoo manufacturers has been found to contain ingredients which are significantly dangerous when introduced into human eyes. Both of these products employ polyoxyethylene group surface active agents together with a quaternary compound as the active principles of the so-called dry shampoo. The two manufacturers had acquired wide distribution, but had received a considerable number of complaints from customers whose eyes had been injured by inadvertent contact with the shampoo material. Pharmacological tests on animals made by this Administration confirmed the dangerous character of the material when introduced into the eye, and demonstrated that the products have the property of producing an opacity of the cornea, which impairs the eyesight for a persistent period of time, if not permanently. Accidentally getting shampoo material into the eye is such a common occurrence in the experience of everyone that such occurrence is consistent with the conditions that are customary or usual in shampooing the hair.
>
> After an initial seizure in each instance, these manufacturers agreed voluntarily to remove their products from the market and to attempt to devise suitable substitutes. In neither instance had any pretesting whatsoever been conducted by the shampoo manufacturers, notwithstanding the fact that data are generally available which would suggest the extreme likelihood that such ingredient would be dangerous. Again, these ingredients, particularly the polyoxyethylene compound, are in the nature of a mixture rather than a chemical entity and the effects of one batch may not be safely forecast from tests made upon another, unless the entire group of possible compounds is tested and found innocuous.

Was one of these shampoos your product?

Mr. LEVIN. Yes.

Mr. KLEINFELD. You said that the injury which had been caused was just an irritation, whereas the Food and Drug Administration said that an opacity of the cornea was caused which impaired the eyesight for a persistent period of time, if not permanently.

Would you call that a temporary irritation?

Mr. LEVIN. The complaints that we had were, as I described them. The tests of the shampoo on laboratory animals could produce the corneal opacity.

Mr. KLEINFELD. And you changed the formula some time after you had received complaints and the Food and Drug Administration had communicated with you; is that not right?

Mr. LEVIN. Yes, that is correct.

Mr. KLEINFELD. And your product was seized by the Government, was it not?

Mr. LEVIN. Yes; prior to the time of our recall.

Mr. KLEINFELD. Is it not a fact that with respect to your older formula, which was used in the shampoo which caused this eye injury, you really didn't conduct any testing?

Mr. LEVIN. Yes; on animals, that is correct.

Mr. KLEINFELD. Well, what tests did you perform?

Mr. LEVIN. As I said before, we had used the shampoo on performance tests.

Mr. KLEINFELD. You used the shampoo on how many people?

Mr. LEVIN. Exactly how many——

Mr. KLEINFELD. Exactly how many, if you recall. If not, approximately how many people did you use this shampoo on?

Mr. LEVIN. There must have been a dozen people around the place. Then we had some local beauty parlors testing the shampoo for a period of time.

Mr. KLEINFELD. How did they test it?

Mr. LEVIN. Just for performance. It hadn't occurred to us to test it for eye injury.

Mr. KLEINFELD. They used it on people who came in for shampoos?

Mr. LEVIN. Yes.

Mr. KLEINFELD. That was testing after the sale, was it not?

Mr. LEVIN. Yes.

Mr. KLEINFELD. And it did not occur to you that the shampoo might get into the eye of a person using it?

Mr. LEVIN. The fact that the product might not be safe had not occurred to us and the testing had not.

Mr. KLEINFELD. What other products do you make?

Mr. LEVIN. We make shampoos of various types, as listed, and we get into permanent wave lotions, several manicuring preparations.

Mr. KLEINFELD. Permanent wave lotions?

Mr. LEVIN. Yes.

Mr. KLEINFELD. Did you test those products in any way?

Mr. LEVIN. No, sir; we have not. Those products we have been manufacturing for many years—15 to 20 years.

Mr. KLEINFELD. With respect to those products which are used on the face or on the hair or on the head, did you put them in the eyes of any experimental animals or the eyes of people before you marketed them?

Mr. LEVIN. No, we didn't. It was not until we had had this meeting with the Food and Drug that we learned the method for such testing.

Mr. KLEINFELD. How soon after you got the first complaint about your shampoo did you take any steps at all to withdraw your product from the market?

Mr. LEVIN. The first complaint was February. The second one was March or April, at which time inspectors from the Food and Drug Administration came into the place to check up on the details of the product, manufacturing procedure, and that was about 6 months prior to the next complaint, at which time we were advised by the Food and Drug Administration of the potentially dangerous aspect of the product.

Mr. KLEINFELD. When did you recall your product?

Mr. LEVIN. At the end of August, before the beginning of September.

Mr. KLEINFELD. So that, although you received complaints beginning in February, you did not take steps to remove your product from the market until late in August, or early in September; is that right?

Mr. LEVIN. That is correct.

Mr. KLEINFELD. Now, after this experience with your shampoo, you then conducted tests and changed your formula; is that correct?

Mr. LEVIN. Yes, sir.

Mr. KLEINFELD. Did you take steps to perform adequate testing on all the balance of your cosmetic line?

Mr. LEVIN. That is in process now. We have already started running some of the products; and we are working on a plan to have the complete line tested for toxicity.

Mr. KLEINFELD. Meanwhile, however, all your products are being sold on the market?

Mr. LEVIN. Yes.

Mr. KLEINFELD. After the experience with your shampoo which caused this eye damage, did you consult any eye specialists or other doctors?

Mr. LEVIN. We discussed the problem with an independent toxicological laboratory, a physician——

Mr. KLEINFELD. What did he tell you?

Mr. LEVIN. Pardon me?

Mr. KLEINFELD. What did he tell you?

Mr. LEVIN. Well, the Food and Drug Administration pointed out the tests on rabbits, and we were referred to the method of testing and the procedure, and it was apparent that according to this technique the product was dangerous to sell.

Mr. KLEINFELD. Didn't this doctor tell you that the ingredients contained in your shampoo were capable of causing severe eye injury?

Mr. LEVIN. We had agreed on that point when the information was pointed out.

Mr. KLEINFELD. No further questions.

The CHAIRMAN. How many products do you manufacture?

Mr. LEVIN. I have them listed here.

The CHAIRMAN. About how many of them?

Mr. LEVIN. It looks like 27 listed.

The CHAIRMAN. Will you describe to us how you mix those products in your factory? Do you make them up in batches?

Mr. LEVIN. Yes, sir.

The CHAIRMAN. And how many gallons would you make up of a product, say, at a time?

Mr. LEVIN. It depends on the particular product. Some batches are 1,000 gallons, other batches are 1,500 gallons, others might just be 50 gallons.

The CHAIRMAN. And what precautions do you take in adding the amount of each ingredient called for in the formula?

Mr. LEVIN. A formula card is written up in the laboratory for the particular batch, and it is taken out into the plant where the items are weighed out and checked and put into the batch.

The CHAIRMAN. Who does this work?

Mr. LEVIN. We have batch makers in the plant that do that.

The CHAIRMAN. Are they just skilled mixers?

Mr. LEVIN. Yes.

The CHAIRMAN. Or are they men with any technical attainments?

Mr. LEVIN. They are skilled mixers.

The CHAIRMAN. And after a batch is mixed up, do you take a sample of that batch?

Mr. LEVIN. That batch is sampled and brought into the laboratory, where various chemical or physical tests are performed on it to assure us that the mixture is as it should be and conform to the various standards that are set up.

The CHAIRMAN. And who actually supervises it, the one man you described as the man who takes the sample?

Mr. LEVIN. Yes.

The CHAIRMAN. And he makes the laboratory tests of each of these mixtures?

Mr. LEVIN. Yes.

The CHAIRMAN. Each sample from each lot?

Mr. LEVIN. Yes.

The CHAIRMAN. And do you keep that sample on hand for any length of time?

Mr. LEVIN. Yes. We keep the samples on hand for quite a period of time with the batch number on it, and the batch card is kept along with the particular tests that were conducted on that batch.

The CHAIRMAN. Is there anyone who checks on these ingredients? Before they are put into your mixture?

Mr. LEVIN. Some of the raw materials are checked and others are not checked before they go in.

The CHAIRMAN. Then you take a man who is not a trained chemist and allow him to compound all of these ingredients. Isn't a mistake likely to happen? I want to know what precautions you take to guard against mistakes.

Mr. LEVIN. The testing of the finished batch would be off on various standards if incorrect products were put into the batch.

The CHAIRMAN. Let's see, then. You mean that your chemist is able to analyze that product and tell just how much of each product has been put in after it is already compounded and mixed?

Mr. LEVIN. No. There are certain tests that are very informative, such as free alkali or moisture tests—pH determinations, or——

The CHAIRMAN. Suppose you take a wetting agent. You know what a wetting agent is, do you—an emulsifier. You use an emulsifier in these batches, do you not?

Mr. LEVIN. Yes.

The CHAIRMAN. To combine the fatty ingredients with water and other ingredients, is that right?

Mr. LEVIN. Yes, sir; an emulsifying agent.

The CHAIRMAN. And who checks on that wetting agent? And after that wetting agent is added, could you determine how much was put in there?

Mr. LEVIN. That would probably depend on the particular product that is being made up.

The CHAIRMAN. I don't expect you to be an expert, but there is no way of determining, is there, just how much of this wetting agent has been added when you take a sample of the finished product?

Mr. LEVIN. That is probably correct.

The CHAIRMAN. Have you thought of whether or not there should be any Government supervision in the plant where you mix these ingredients?

Mr. LEVIN. I haven't thought of it from that aspect.

The CHAIRMAN. Don't you think there should be at least a double check on this—the ingredients should be first set aside and then a second person should check on the ingredients and each one indicate that he has made such an inspection before it is allowed to be compounded and sold to the public?

Mr. LEVIN. Yes; that should be done.

The CHAIRMAN. That is an ordinary precaution?

Mr. LEVIN. Yes.

The CHAIRMAN. You don't take that precaution, do you?

Mr. LEVIN. Yes; we take that.

The CHAIRMAN. That is what we are trying to get at.

Mr. LEVIN. Yes; that material is double-checked before it goes into the batch. I am sorry if I didn't make that clear.

My two batch makers usually work together on a product, and then there is the chemist. The chemist in most cases will even check the materials before they are pumped in or mixed into the batches.

The CHAIRMAN. Have you an automatic pump gage? Have you gages there that indicate the amount that is pumped?

Mr. LEVIN. Most of the material pumped in is weighed.

The CHAIRMAN. Or do you work between two floors by gravity?

Mr. LEVIN. Yes; we have two floors.

The CHAIRMAN. Do you work by gravity, put the mixture up above, and then when it is all ready put it into the mixer? Have you a stock room from where you draw these ingredients?

Mr. LEVIN. Yes.

The CHAIRMAN. And is a check made each night on the inventory as to how much was contained in that stockroom each morning and how much was taken out each day?

Mr. LEVIN. There is no perpetual inventory of the raw materials. The quantities of chemicals are checked as they are used and rechecked.

The CHAIRMAN. I didn't understand the rechecking, but if you say they are rechecked, that is the point I am trying to get at.

Mr. LEVIN. Yes.

The CHAIRMAN. Any questions, Dr. Hedrick?

Dr. HEDRICK. How long has your company been in business?

Mr. LEVIN. Since 1930—21 years.

Dr. HEDRICK. How many products have you had difficulty with, the same as this shampoo you had on the market? Have you had any trouble with other products?

Mr. LEVIN. No, sir; we have not.

Dr. HEDRICK. This shampoo was the first one you had trouble with?

Mr. LEVIN. Yes, sir.

Dr. HEDRICK. With 21 years of service, you have a pretty good record then, do you not?

Mr. LEVIN. We like to think of it that way.

Dr. HEDRICK. And you make about how many products? Did you say 27?

Mr. LEVIN. Something like that.

Dr. HEDRICK. How many types of shampoo do you make?

Mr. LEVIN. I believe I counted 12 here before when I was going through the list.

Dr. HEDRICK. How long has your present chemist been with you?

Mr. LEVIN. Over 10 years.

Dr. HEDRICK. That is all, Mr. Chairman.

The CHAIRMAN. Mr. McDonough.

Mr. MCDONOUGH. What percentage of your production is bottled for the trade, for the consuming trade, over the counter?

Mr. LEVIN. Most of our business is through the beauty-shop jobbers, who in turn sell it to the beauty parlors for use, and very little of it goes into drug stores. We have a certain amount sold through some direct selling companies.

Mr. MCDONOUGH. What percentage, and what products particularly, go over the counter in small quantities to the trade? Would you say 10 percent, 5 percent?

Mr. LEVIN. Probably 25 or 35.

Mr. MCDONOUGH. 25 or 35 percent of the total production of the plant goes in bottles to be sold over the counter under brand names?

Mr. LEVIN. That would just be an estimate. I really haven't figured it.

Mr. MCDONOUGH. In other words, you don't cater to that business; you don't cater to the over-the-counter trade?

Mr. LEVIN. That is correct.

Mr. MCDONOUGH. But to the beauty shops and barber shops, which I suppose you also sell to?

Mr. LEVIN. Yes.

Mr. MCDONOUGH. To the beauty shops and barber shops. Where do you sell outside of New York City? Do you have any extensive trade along the Atlantic seaboard, or the Midwest?

Mr. LEVIN. I would say it gets around the country this side of the Mississippi without any particularly heavy market.

Mr. MCDONOUGH. And do you pick your distributors, or do you let anyone who wants to buy from you? Do you have a select trade?

Mr. LEVIN. No; we sell to——

Mr. MCDONOUGH. Anyone?

Mr. LEVIN. Any legitimate jobber in the business.

Mr. MCDONOUGH. How long have you been using most of these synthetic chemicals in the production of your products?

Mr. LEVIN. Well, the offending product is less than 2 years old, but some of the other synthetics we have been using for possibly 10 years or longer.

Mr. MCDONOUGH. So, back 10 years ago you were not using so many of them, and as you added them to your inventory did you check with the Food and Drug Administration, or the manufacturer that produced them, as to the purity of the material and the testing and what effect it would have on your product?

Mr. LEVIN. Yes; we always checked with the suppliers of the raw material for their recommendations.

Mr. MCDONOUGH. And the effect it will have on your product?

Mr. LEVIN. Well, we wouldn't use a product, a raw material, if it were not recommended for the particular finished product we are going to manufacture.

Mr. MCDONOUGH. Wait a minute. Do you buy the chemicals recommended by the manufacturer to be used in your product or do you pick them to use in your product?

Mr. LEVIN. We pick them, but we do consult with the manufacturers of the basic materials.

Mr. MCDONOUGH. And have you been in the habit of reporting to the Food and Drug Administration that you are adding a new chemical to your product?

Mr. LEVIN. No, sir; we have not.

Mr. MCDONOUGH. It hasn't been a customary practice with you?

Mr. LEVIN. No; it hasn't.

Mr. MCDONOUGH. In other words, is this last incident that you had the only one in which the inspectors came along and wanted to check your manufacturing processes?

Mr. LEVIN. No. We have routine inspections approximately once a year or once every other year.

Mr. MCDONOUGH. What are those inspections for—sanitation or efficiency, or what purpose?

Mr. LEVIN. Well, I imagine its purpose is to include both of those, and they have also taken samples of our labels and copied our formulations. They have had records of the formulas for, I don't know how many years. I do know the last couple of years.

Mr. MCDONOUGH. In other words then, the Food and Drug Administration has known what has been going into your products for the last 10 years?

Mr. LEVIN. I don't know if it goes back 10 years, but I know certainly the last several years.

Mr. MCDONOUGH. That they have known what your products contained, all of your products?

Mr. LEVIN. Yes, sir. They came in specifically approximately a month after a routine inspection at which time the formulation was given to them.

Mr. MCDONOUGH. Did they ever caution you on the amount of any of the chemicals that you were using? Or you don't give them the quantity, of course?

Mr. LEVIN. Yes; we do.

Mr. MCDONOUGH. You do?

Mr. LEVIN. We have given them the complete formulas.

Mr. MCDONOUGH. Did they ever caution you about not using too much of any one particular chemical or another?

Mr. LEVIN. No; they haven't.

Mr. MCDONOUGH. I mean generally, I don't mean any specific isolated incident. Have you ever been cautioned by them about not using any of them?

Mr. LEVIN. No; and the point I was trying to clear up was that this inspection that was specifically as a result of the complaint on the shampoo was about a month after the routine inspection at which time we had given them our formulation.

Mr. MCDONOUGH. I see.

Mr. LEVIN. The second time they had taken the formula again and compared various batches, and they asked us what testing we had done or were doing on it. We told them, and there were no suggestions that came that we should test it on animals.

The CHAIRMAN. Is it not a fact that a mere reading of the formula would not tell you or the Food and Drug Administration, or anybody else that damage would occur?

Mr. LEVIN. I believe that is right.

The CHAIRMAN. It did not occur to you that using the formula would hurt anybody?

Mr. LEVIN. That is right, exactly right.

The CHAIRMAN. You have to make the tests in order to find out?

Mr. LEVIN. Yes, sir. The time that I was concerned was when they came as a result of the complaint and it was specific for the product.

The CHAIRMAN. The Food and Drug Administration is not supposed to test your material, is it?

Mr. LEVIN. No; it isn't. But that was one of the points I tried to make as being possibly a helpful suggestion—if there could be a direct line of communication from the Food and Drug Administration to be advisory, along with its other functions, so that if they should get a complaint from any one of these raw materials or products, they could possibly notify the industry directly and in that fashion anyone using these products or similar products could check into it immediately.

It would prevent that much more goods from getting out into the market that might harm the public.

The CHAIRMAN. But of course nothing has prevented you from conferring with the Food and Drug Administration at any time; is that correct?

Mr. LEVIN. No, sir.

The CHAIRMAN. That is all. You are excused.

Mr. LEVIN. Thank you.

The CHAIRMAN. The next witness.

Mr. KLEINFELD. Dr. Pillsbury.

The CHAIRMAN. Your name and address, Doctor?

Dr. PILLSBURY. Donald M. Pillsbury, University Hospital, University of Pennsylvania, Philadelphia, Pa.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF DONALD M. PILLSBURY, M. D., PROFESSOR OF DERMATOLOGY, UNIVERSITY HOSPITAL, UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE, PHILADELPHIA, PA.

Mr. KLEINFELD. Are you located in Philadelphia, Doctor?

Dr. PILLSBURY. Yes, sir.

Mr. KLEINFELD. Where did you receive your medical degree?

Dr. PILLSBURY. University of Nebraska.

Mr. KLEINFELD. What year?

Dr. PILLSBURY. 1926.

Mr. KLEINFELD. How long have you specialized in the field of dermatology?

Dr. PILLSBURY. Since—you mean in practice or in training?

Mr. KLEINFELD. Training.

Dr. PILLSBURY. Well, I started to train in dermatology in 1928.

Mr. KLEINFELD. And you have practiced in that field since when?

Dr. PILLSBURY. Well, I started practice in 1934.

Mr. KLEINFELD. Are you a fellow of the American Medical Association?

Dr. PILLSBURY. Yes, sir.

Mr. KLEINFELD. And are you certified by the American Board of Dermatology and Syphilology?

Dr. PILLSBURY. Yes, sir.

Mr. KLEINFELD. Are you a member of the American Dermatological Association?

Dr. PILLSBURY. Yes, sir.

Mr. KLEINFELD. And of the American Academy of Dermatology and Syphilology?

Dr. PILLSBURY. Yes, sir.

Mr. KLEINFELD. And of the American Clinical and Climatological Association?

Dr. PILLSBURY. Yes, sir.

Mr. KLEINFELD. And you are professor of dermatology and syphilology in the University of Pennsylvania School of Medicine?

Dr. PILLSBURY. Yes, sir.

Mr. KLEINFELD. Have you contributed papers to the professional publications in the field of dermatology?

Dr. PILLSBURY. Yes, sir.

Mr. KLEINFELD. About how many, would you say?

Dr. PILLSBURY. I don't know exactly. I think around 75; something of that sort.

Mr. KLEINFELD. All in the field of dermatology?

Dr. PILLSBURY. To some extent in syphilology and also reasonably basic studies in chemistry of the skin in relation to other organs and so forth.

Mr. KLEINFELD. Please read your statement.

Dr. PILLSBURY. This is a statement upon the advisability of legislation which would make cosmetics subject to the same rules and regulations as to nontoxicity and safety as are presently in force in respect to drugs having, or reputed to have, specific medical actions when applied to the human skin. I strongly favor such legislation because (1) certain types of cosmetics have unquestionably produced moderate to severe damage to the human body in the past; (2) a very large number of chemical compounds having potential uses in cosmetics have become available during the past 10 years, and many others are in process of development; (3) under present regulations it is entirely possible for a manufacturer to introduce a new cosmetic to the public with almost complete disregard of the safety of the compound; (4) cosmetics are used upon the normal or abnormal human skin without any medical supervision whatever and hence should possess an extremely high margin of safety; and (5) cosmetics not infrequently contain active compounds which have definite physiologic effects but are, nevertheless, offered primarily as aids to beauty with resultant excessive use.

It is quite true that the majority of cosmetics in common use today are composed of ingredients which have long been used on the human skin and have been shown to be harmless except in isolated instances of unusual individual sensitivity. The experience with these waxes, oils, pigments, and so forth, has, literally, been accumulated through the ages. It is also true that certain compounds have been introduced to the public with inadequate prior study, and have then been slowly discontinued because of increasing evidence of true toxic-absorption effects or of a high capacity to produce sensitization of the human skin.

I would like to cite a few illustrative examples. Some years ago, on the basis of the fact that salts of the metal thallium would produce loss of hair, a preparation called Koremlu, containing thallium acetate, was introduced for application to areas of the skin where unwanted hair was growing. Koremlu produced loss of hair as advertised; it also, if used long enough, inevitably produced severe damage of the liver, nervous system, and other tissues, because the active ingredient was easily absorbed through the skin and had definite and consistent poisonous effects. Any competent medical scientist could have predicted this effect, but there was no bar to the manufacture and sale of the compound possible until it had disabled some of its users.

Mr. McDonough. How do you spell that?

Dr. Pillsbury. K-o-r-e-m-l-u. The metal is thallium.

Mr. McDonough. Thank you.

Dr. Pillsbury. A few years ago, a new and cosmetically satisfactory nail-polish base was introduced by several manufacturers. The largest manufacturer of this compound had employed it on a trial basis in several hundred women—I don't know exactly how many. That is what I was told—but it soon became evident that these trials had not been extensive or prolonged enough, because the compound produced loosening of the fingernails and inflammation of the ends of the fingers in a high percentage of users.

Hair dyes, principally paraphenylenediamine compounds, have long been a source of difficulty. It is now well recognized by experienced beauty operators that a preliminary patch test to determine possible sensitivity to the dye should always be carried out as a precautionary measure before the hair is dyed. Nevertheless, compounds of this general class—that is hair dyes and so forth—are constantly being reintroduced, usually with a meaningless catch-phrase, such as "eggplant catalyst X," always with an advertising campaign of remarkable scope and effectiveness, and with the assistance of veteran cosmetic salesmen of the competence of Somerset Maugham. To my knowledge, the packages of such "new" hair dyes rarely contain any statement as to the exact nature of the contents and, as a physician, I am forced to depend upon hearsay information and advertising gobbledegook in advising patients as to whether or not their skin disease may be due to the compound in question.

Following the introduction of sulfonamides into medical practice, the local application of this group of compounds to the skin in the prevention or cure of bacterial infections became quite common. It was not until these compounds had been used in over 200 patients over considerable periods of time that my associates and I began to realize that such local application sensitized the skin in a high proportion of users, at least 20 percent. Unfortunately this sensitivity often did not become evident until sulfonamides were given to the patient later by mouth for the treatment of a serious infection such as pneumonia or erysipelas. Some 2 years after reporting in the medical literature on this reaction, I was understandably surprised to note that the manufacturer of a widely used brushless type of shaving cream had begun to incorporate sulfathiazole in this cream in a strength of 1 percent. At that time, 1945, it appeared for sale in the post exchanges of the United States Army. Since I was the consultant in dermatology

in the European theater of operations, and since sensitization to sulfonamides was then a major source of disability from skin diseases, immediate suspension of sale of this preparation was possible. Under ordinary conditions of protection of the health of civilian population, and under existing civil laws, however, it would not have been possible until a number of complaints had been made, suits filed, and the board of directors of the company convinced by reason of financial considerations that the sale of such a harmful preparation would be unwise.

The synthetic detergents are another group of compounds now in common use, which are proving to have harmful effects in a considerable number of persons. Since these compounds are primarily intended for the washing of clothing or dishes, their inclusion in a consideration of cosmetics might be debated. Nevertheless, in their use they come in contact with the human skin for prolonged periods of time, and have harmful effects on many users. Extremely chronic and disabling eczema of the hands may result. As a physician, I am much interested in the extent of the tests by the manufacturer to determine whether or not such products were safe for prolonged contact with the human skin. I am confused by the manufacturer of a soap and of a synthetic detergent suggesting strongly that if his detergent irritates, one should use his soap. One is tempted to add a qualifying phrase to the slogan "Kind to Your Hands (no fingers have dropped off yet)."

Another group of compounds on which one might desire more accurate information are the so-called rejuvenating creams in which a hormone, usually an estrogenic substance, is incorporated. Such compounds are readily absorbed through the skin, though at uncertain rates. They may well be of significance, when used indiscriminately, in promoting the growth of cancer in various organs of the body, such as the breast.

As a physician whose particular special interest has been in diseases affecting the skin, and as the director of a rather large group of university scientists interested in the mechanisms by which disability from skin diseases is produced, I would like to say a few words in behalf of this large and essential organ of the body, and some of the means by which we, as occupants of skin, interfere with its normal protective and physiologic functions.

I am sure that all of you will agree that the normal human skin does an admirable job of protecting the individual it contains. It is essential in the regulation of our body temperatures; it warns us of physical injury; it protects us from too much heat, cold, or sunshine; it promptly kills most harmful bacteria which come to rest upon its surface; it ordinarly heals quickly when it is injured; in short, given half a chance, the skin, as the largest organ of the body, does a varied and essential job with little complaint. It is, however, in a particularly vulnerable position. If it becomes diseased, no matter in how minor a fashion, it is subjected to a wide variety of treatments suggested by the patient's relatives, friends, and physicians. In the view of modern cosmetology, the normal skin is never quite perfect. We are subject to a constant stream of suggestion through the press, radio, and television that it is too dry; it is too oily; it is coarse; it smells offensively; it develops too many pimples; it may give rise to a cancer any minute; it is covered with fungi; it crawls with germs; it has

adolescent pimples; it is wrinkled and old; it makes one undesirable to one's boy friend or mistress, or husband, or wife, or employer; it sunburns too rapidly; it tans too slowly; it grows too much hair; it grows too little hair; the hair is the wrong color; the nails split; the nails should be red—not purple, as suggested last spring; the hair is too straight—or too curly; the skin needs vitamins; it needs minerals. Under such a stream of suggestions it is not surprising that neuroses develop and flourish, and that the human skin is subjected to a multiplicity of drying, oiling, massaging, tinting, hair curling, and general beautification and protection procedures which are utterly staggering to contemplate. These procedures are by no means all devoid of risk.

I think it is perfectly clear that during the past decade women are using far more cosmetics. I don't know what the sale of them is, but I know that I hesitate now in practice in asking a woman what cosmetics she uses, unless I have a spare half hour to spend. And, as a rule, she will forget 8 or 10 and tell you about them when she comes back next week. It really is quite staggering.

Now if each cosmetic has even a slight risk to it, the accumulative risk becomes more. I think we are running into that right along—people exposing themselves to 20 or 25 things instead of 5, and the amount of risk increases.

I would venture to suggest that the original definition of cosmetics, "materials for purposes of adornment," has long been out-stripped, and that many such preparations now have significant medical implications and, as such, are properly in the field of public health and preventive dermatology. As a physician, I have no direct concern with methods of adornment, but I think that one may properly insist that this adornment be without significant risk to health.

Certain principles and facts bear on this general problem, and are stated briefly herewith:

1. The normal human skin may be injured by substances applied to it, in several ways, as follows:

(*a*) By immediate chemical irritation, strong acids, corrosives, etc. Such irritating capacity may ordinarily be determined very easily by patch tests in a small number of subjects (10 to 25).

(*b*) By irritation produced by repeated and prolonged contact with substances such as detergents, abrasives, and defatting agents. Patch tests may be quite worthless in predicting the irritating effect of such compounds. Prolonged usage tests in at least 100 subjects are necessary.

(*c*) By sensitization of the upper layers of the skin. Prediction of the sensitizing effects of a particular chemical is very difficult with presently available methods.

The classic example of induced sensitization is to poison ivy. Infants at birth are almost never sensitive to suitable dilutions of poison ivy extract. Seventy percent of persons of 40 years or more are sensitive. This sensitivity has been induced by repeated intermittent contact with poison ivy over a period of many years. This same principle holds true for every other sensitizing chemical.

Poison ivy is therefore a compound with a high sensitizing index. It is essential that, in the case of any new chemical which is to be applied repeatedly to the human skin, this sensitizing index be determined. It has been found, for instance, that, topically applied, peni-

cillin, sulfonamides, and streptomycin all have such great capacity for sensitization as to make their use on the human skin very inadvisable. In determining such capacity, "prophetic" patch tests in at least 100 subjects are essential, and, if these are satisfactory, prolonged usage tests in 200 or more subjects under competent medical observation. Certain refinements in the determination of sensitizing capacity are now under study, but have not yet reached a practical level.

2. The abnormal human skin, inflamed or otherwise diseased, is even more subject to direct chemical injury or sensitization. In the case of cosmetics, it is generally assumed that they will not be used on diseased skin. This is not the case.

3. The amount of disability due to diseases of the skin is not generally realized, in part because such diseases are not reportable, and rarely cause death. However, Armed Forces statistics during the recent war give a reliable index of the extent of this disability, as follows: This disability is not due to cosmetics. I would emphasize that. But I just want to give you data indicating that skin diseases do cause people trouble and may cause them to go into hospitals.

(*a*) During the war, in temperate climates, between 7 and 10 percent of admissions to Army hospitals were because of skin diseases.

(*b*) In tropical climates, 20 or 25 percent of hospital admissions were due to a skin disease, and under such conditions, 50 percent or more of soldiers reporting at sick call did so because of a skin disease.

(*c*) The number of patients evacuated because of skin disease from the Pacific theaters of operation to the United States during the war considerably exceeded those evacuated because of wounds, and in many months exceeded all other causes of evacuation with the exception of neuropsychiatric disease.

(*d*) It has been estimated that almost 50 percent of patients admitted to a hospital because of a skin disease require this because of a sensitization reaction to an applied chemical substance. Those are usually medical substances in military practice. I am not talking about cosmetics now. But in civil practice cosmetics play a good sized role in producing that disability.

4. In the practice of clinical or preventive medicine, and certainly even more so in the use of cosmetics, it seems to me a sound scientific and moral principle that the remedy or treatment being used should under no circumstances be capable of producing disability or disease more serious than the one being treated. If this sound principle is applied to cosmetics, which are presumed to be only for the purpose of improving the appearance of the skin, and its appendages, very little risk from the cosmetic itself is justified.

In summary, may I express my firm agreement with the advisability of placing cosmetic preparations under the same restrictions to insure safety to the American public as are presently applicable to foods and drugs. While the vast majority of cosmetics presently on sale are safe, and eligible for prompt approval in this regard, there are others concerning which I would have grave doubts. More particularly, the constant development of numerous new synthetic materials which have potential cosmetic application, requires the evolution of adequate standards of safety in terms of toxic absorption, direct chemical irritation to the skin, eyes, and mucous membrances, and potential sensitizing effects. This must be done by an impartial agency such as the Food and Drug Administration; I believe that the manufacturers of

cosmetics would have great difficulty in arriving jointly at satisfactory standards of safety, and I would have no confidence in enforcement of such standards except by public law.

I am sorry to have been so long.

The CHAIRMAN. That is perfectly all right.

Mr. Kleinfeld?

Mr. KLEINFELD. Doctor, I gather from your statement that you think the use of untested substances in cosmetics does present a rather serious problem.

Dr. PILLSBURY. Yes, sir; I do.

Mr. KLEINFELD. The Federal Food, Drug, and Cosmetic Act, in section 201, defines cosmetics and thus brings them within the coverage of the law as far as the law goes, but specifically excludes soaps.

Dr. PILLSBURY. Soaps?

Mr. KLEINFELD. Yes. Do you know of any sound reason why soaps should be excluded whereas cosmetics are included?

Dr. PILLSBURY. No, sir; I don't.

Mr. ABERNETHY. Mr. Chairman?

The CHAIRMAN. Yes.

Mr. ABERNETHY. Mr. Chairman, if Mr. Kleinfeld will yield, I would like for him to state for my information, and for the benefit of the record at this point, just what authority the Food and Drug Administration now has in the field of policing the distribution of cosmetics.

Mr. KLEINFELD. Do you want me to answer that now?

Mr. ABERNETHY. Yes.

Mr. KLEINFELD. As the law now stands, if a manufacturer puts out a cosmetic or a food, and it proves to be dangerous——

Mr. ABERNETHY. They condemn——

Mr. KLEINFELD. The Food and Drug Administration can then seize the product and prosecute the manufacturer.

Mr. ABERNETHY. The law for cosmetics is identical with that for food now?

Mr. KLEINFELD. That is right.

Mr. ABERNETHY. I didn't know.

Mr. KLEINFELD. The Food and Drug Administration has to start a lawsuit, either civil, by seizure of the property, or a criminal action against the distributor.

The CHAIRMAN. They must notify——

Mr. KLEINFELD. They must start a legal proceeding in a court of law and prove to the satisfaction of a court and jury that the product may be injurious. It need not be pretested, as in the case of a new drug.

Mr. JONES. Pardon me. That is what I want to bring out here.

In the last paragraph of the doctor's statement he expresses his "firm agreement with the advisability of placing cosmetic preparations under the same restrictions to insure safety to the American public as are presently applicable to foods and drugs."

That leaves the impression it was the same law that applied.

Dr. PILLSBURY. I was not aware of that, sir. I mean, as applicable to new drugs, certainly, where there is pretesting.

Mr. JONES. That is what I wanted to distinguish, Doctor, because there is a difference. One puts the burden in one place and——

The CHAIRMAN. Without objection we will strike out "food."

Dr. PILLSBURY. I would appreciate that.

Mr. JONES. Pardon me. I don't think that that should be stricken from the statement, because I think that is the thing that has brought this committee into being and is one of the points we are making here now—the difference in the application.

The CHAIRMAN. He is citing that as an example, and by just striking the one word "food"——

Mr. JONES. I know, but the statement he has made here has left the impression that I think is general with a lot of people.

The CHAIRMAN. That is true.

Mr. JONES. And by striking that out, then you take away the effect of the statement that he has made, and I think we should leave that in the record to show that there is a confusion among the public. I think the public generally is confused, and I think we ought to leave it in there.

The CHAIRMAN. I think the doctor is interested in drugs, and he assumed that what applies to drugs would surely apply to the food you use every day in the week.

What we were speaking about was eliminating the word "food" and letting "drug" remain. Is that right?

Dr. PILLSBURY. Yes. I was thinking also not only of drugs used under prescription, but those sold over the counter.

The CHAIRMAN. Of course, any drug.

Have you objection to that, Mr. Jones?

Mr. JONES. I still think, after the explanation, when you change his statement there we are losing the effect of the statement that he made before the explanation was given to him. In other words, he had made this statement here. As I understand it, Doctor, you were under the impression that the same regulations applied to food as applied to drugs. Is that correct?

Dr. PILLSBURY. I don't pretend to——

Mr. JONES. I am asking whether it was your impression when you made the statement.

Dr. PILLSBURY. I think that is readily explained by the joint use of terms in Food and Drug Administration all the time.

Mr. JONES. That is what I am saying. So I think you were under the impression the same regulations applied to food and drugs.

Dr. PILLSBURY. I was familiar only with the regulations with regard to drugs.

The CHAIRMAN. I dare say any member of this committee was not familiar with the fact there was a difference between drug and food laws when this committee was started.

Mr. JONES. That is true, and that is why I think we ought to leave it so everyone could see the confusion that exists.

Mr. ABERNETHY. Since we are all confused, let's proceed.

The CHAIRMAN. Go ahead.

Mr. KLEINFELD. I think from what you just said, Dr. Pillsbury, you might have the same problem with soaps, which are often used as cosmetics, that you pointed out with respect to cosmetics; is that correct?

Dr. PILLSBURY. Yes; I think so. That is, we have soaps, standard soaps, that have been used for hundreds of years and newer, more refined soaps that have been introduced in the last 25 years. And we have the surface active agents, detergents, that are being used widely.

I would like as a physician to advise patients knowing just a little bit more about these detergents, being able to get more information, being absolutely sure that these had been tested on the human skin. This problem of hand eczema is no laughing matter, it is awfully tough. You see it in surgeons, you see it in young mothers, for instance, and unfortunately after the reaction has been produced, it may stay there for years long after the original cause has been removed. It is one of the most difficult problems we encounter in the treatment of skin diseases. Some patients we just unfortunately can't cure, but the big problem there is prevention, not cure after the thing has happened.

Mr. KLEINFELD. For example, we had the situation this morning where we discussed the case in which a shampoo had been put out on the market containing a wetting agent and a quaternary compound which caused fairly serious eye injury. In your opinion, is it conceivable that soap might be put on the market containing those ingredients or other similar ingredients?

Dr. PILLSBURY. There are compounds containing detergents; yes. There are soap substitutes.

If I may just go back—in the matter of these soapless shampoos the information was easily available, and it was available 10 years ago, to show those compounds could not be used in the human eye. We have done some work on it, and there was a good deal of work done in connection with ointments to be used as preventives against poison gases which were supposed to be used in the eye, and it was shown you couldn't use those compounds in the eye, they had a bad effect.

Mr. KLEINFELD. Suppose I want to go into the beauty soap business today, and get a corps of advertising experts and publicity men. They advise me to use various ingredients, some of which may be old, and some of which may be new, and it is put on the market. If the kind of testing which you mention in your statement is not performed on that product, is it quite possible that adverse physical reactions may occur?

Dr. PILLSBURY. Providing it is a new formula. That is, an experienced soap chemist could look at it and say, "This is the same formula used 10 years"——

Mr. KLEINFELD. Provided it was a new formula or substance?

Dr. PILLSBURY. That is right.

Mr. KLEINFELD. To that extent it is similar to what you say about cosmetics?

Dr. PILLSBURY. That is right.

Mr. KLEINFELD. You mention patch tests. They are rather important, are they not?

Dr. PILLSBURY. Yes, sir; they have serious limitations, however.

Mr. KLEINFELD. With those limitations you believe that they should be performed?

Dr. PILLSBURY. They should always be performed. They will pick up the very strong sensitizers.

Mr. KLEINFELD. Who should perform them?

Dr. PILLSBURY. Well——

Mr. KLEINFELD. If you know, if you have an opinion.

Dr. PILLSBURY. I think that someone who has had some experience in allergic reactions of the skin, shall we say. I am not pumping for

any particular medical specialist group. I think it should be done by a doctor in all probability, or possibly by a physiologist, someone of that sort. I think that competence in that regard could be ascertained easily.

Mr. KLEINFELD. Do you think the ordinary person—Mrs. Jones—is competent to perform patch tests and judge the results?

Dr. PILLSBURY. No, sir. They are very difficult to read at times.

Mr. KLEINFELD. How about a beauty shop operator?

Dr. PILLSBURY. I don't believe the average beauty shop operator is competent unless she gets a very marked reaction. She can read that, but she can't read the minimal one.

Mr. KLEINFELD. She might not be able to read the reaction which a trained doctor might be able to read; is that right?

Dr. PILLSBURY. Yes. You look at it under a good light, wait for a while afterwards, ordinarily for an hour, and read them again. We are even seeing where it interferes with sweating in the area because that reaction clogs up the sweat glands.

Mr. KLEINFELD. Doctor, another provision of the Federal Food, Drug, and Cosmetic Act, section 601 (a), provides as follows and I would like to get your reaction to it:

> A cosmetic shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof. * * *

Then it goes on to say:

> *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing.

If such a coal-tar dye is used in a product employed in the beauty parlor, do you believe it is safe to permit the ordinary beauty-parlor operator to make these tests on a product which, if it gets in the eye, may possibly cause blindness? Do you think that is enough protection, or do you have any opinion on it at all?

Dr. PILLSBURY. I would prefer not to express an opinion on that.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Mr. Abernethy.

Mr. ABERNETHY. Did I hear you say something about the soapless shampoos a while ago? What did you say?

Dr. PILLSBURY. They were being discussed when I came in this afternoon, and they are so-called dry shampoos which contain detergents, surface active agents.

Mr. ABERNETHY. Do all of them contain that?

Dr. PILLSBURY. I don't know. I know that some of them——

Mr. ABERNETHY. Generally they do?

Dr. PILLSBURY. It is rather difficult, of course, for me as a physician to know what those things contain. I can't tell by looking at the bottle as a rule, there is no place where I can get that information. Sometimes you can and sometimes you can't. But that's been known for some time—if you get too high a concentration of one of these surface active agents in the eye it will produce damage.

(Discussion off the record.)

The CHAIRMAN. Mr. Jones.

Mr. JONES. On page 1 of your testimony, Doctor, you were talking about this Koremlu and you say, "but there was no bar to the manufacture and sale of the compound possible until it had disabled or killed some of its users." Were there some——

Dr. PILLSBURY. That was—oh, yes.

Mr. JONES. There have been deaths reported from that?

Dr. PILLSBURY. There have been deaths reported from that; yes.

Mr. JONES. They were reported as a direct result of the use of this substance?

Dr. PILLSBURY. Yes. My experience with that has been when it was administered by mouth to children to cause loss of hair to cure scalp ringworm infection. I observed three very serious reactions to that. At another hospital I observed one death. That was with the medical use of this compound. I have not personally observed a death from Koremlu. They have been reported in the literature. It is known that thallium is a very toxic substance.

Mr. JONES. What I was getting at—did you have any evidence or information as to whether or not it had been used according to the directions that were printed on the package?

Dr. PILLSBURY. I don't believe those directions mean anything as a rule. A salve is a salve to most people. We tried that. We thought, for instance, in medical practice with a penicillin ointment or with sulfathyozol ointment, if we put on there "Do not use this longer than 5 days," we could prevent reactions. Most people, unless they take a medicine by mouth or it is injected, don't think it can be a poison, just putting it on their skin.

I think it is full of loopholes there. You can't expect the average patient or average user of a cosmetic to always follow the directions. They will slide over them.

Mr. JONES. Now, getting to another question about the use of the synthetic detergents and soaps. Now, of course, you mentioned that these compounds are primarily intended for washing clothes. However, have you had any experience with people being affected by skin irritations or eruptions because of contact with the clothing that had been washed with those compounds? In other words, like a diaper rash, for instance.

Dr. PILLSBURY. Yes, sir; I have had some experience with that. It is very difficult to prove at times. I believe it is due to the detergent that remains. I think that is the general opinion.

Mr. JONES. Then, that would be a matter that would affect some people more than it would affect others due to the sensitivity of the skin?

Dr. PILLSBURY. I think so.

Mr. JONES. We might have two babies that would wear diapers out of the same wash, and it would affect one and would not affect the other?

Dr. PILLSBURY. That is right. My experience has been with direct contact with the skin. I am seeing such patients in large numbers where the irritation has started after a trick detergent has been used.

Mr. JONES. Thank you.

The CHAIRMAN. Thank you, Doctor. We are indebted to you for your testimony.

Mr. KLEINFELD. Mr. Rounds.

The CHAIRMAN. Your name and address?

Mr. ROUNDS. Wellington Rounds, Fairfield Laboratories, Plainfield, N. J.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed, Mr. Kleinfeld.

TESTIMONY OF WELLINGTON ROUNDS, PRESIDENT, FAIRFIELD LABORATORIES, INC., PLAINFIELD, N. J.

Mr. KLEINFELD. You are president of the Fairfield Laboratories?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. And your organization makes only Purity Cross dandruff treatment shampoo?

Mr. ROUNDS. Oh, no.

Mr. KLEINFELD. We asked you to give us a list of all the products you make. Isn't that correct?

Mr. ROUNDS. That is correct.

Mr. KLEINFELD. Have you supplied it?

Mr. ROUNDS. No. I had supplied the committee with a statement and I have supplementary information to that statement.

Mr. KLEINFELD. I asked you whether you supplied the committee with a statement of all the products which you make. That is what we requested of you.

Mr. ROUNDS. I understood the request to be——

Mr. KLEINFELD. Let me read our telegram to you, Mr. Rounds. I have here a telegram dated December 5, 1951, addressed to Fairfield Laboratories, 417 Cleveland Avenue, Plainfield, N. J. Do you remember receiving that telegram?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. Let me read it to you in part:

> Request you have representative appear before the committee at 10 a. m. on January 10, 1952, to read prepared statement setting forth various products manufactured or distributed by you, ingredients contained in these products—

Is that clear?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. Why didn't you do it?

Mr. ROUNDS. I did, with respect to products which might relate to cosmetics.

Mr. KLEINFELD. I ask you again if this Purity Cross dandruff treatment shampoo is the only cosmetic you make.

Mr. ROUNDS. Yes. Therefore, I thought I was complying.

Mr. KLEINFELD. You make no other cosmetics?

Mr. ROUNDS. No, but we do make other products.

The CHAIRMAN. Will you just for our information enumerate one or two? Have you a prepared statement?

Mr. ROUNDS. The prepared statement refers to the Purity Cross dandruff treatment shampoo.

The CHAIRMAN. What other products—just for our own information here—what other products do you manufacture?

Mr. ROUNDS. Insecticide combinations. We are also interested in quaternary ammonium compounds. We do a fair amount of blending and various formulating of different compounds.

The CHAIRMAN. Are they used in the chemical trade?

Mr. ROUNDS. They are used in the chemical field, insecticidal field as insecticides, and some of them are used as chemicals, would be used in formulating by other formulating companies.

The CHAIRMAN. All right.

Mr. ROUNDS. I can give you more detailed information on that if you would like.

The CHAIRMAN. Proceed, Mr. Kleinfeld.

Mr. KLEINFELD. Go ahead and read your statement, please.

Mr. ROUNDS. The statement to you?

Mr. KLEINFELD. The statement to Mr. Delaney.

Mr. ROUNDS. We are manufacturers of a product designated Purity Cross dandruff treatment shampoo which is distributed through the normal channels of merchandising to consumers for the treatment and control of dandruff.

(A list of the ingredients contained in this product is in the files of the committee.)

The standard test for eye irritation for this product prior to marketing is that recommended by the Food and Drug Administration, in which 11 rabbits are used: two of which receive administration of 10 percent of Ivory soap solution in the eye with immediate flushing, three of which receive the concentrated product in the eye with no flushing, three of which receive the concentrated product with 2-second flushing, and three of which receive the concentrated product with 4-second flushing. Examination of the eyes at 24-hour intervals determines the extent or lack of irritation. Lack of indication of serious corneal irritation at 3 to 4 days and a complete lack of irritation to the cornea, eyeball, and surrounding tissue at 7 days indicates a product falling within the tolerances established for this test. The above product was screened in preliminary tests along with other formulae and given the 7-day test prior to marketing. Observation by a competent pharmacological laboratory found the product to fall within the tolerances of the above test.

Since my knowledge of chemicals in cosmetics generally is limited to those employed or rejected by us, I am not in position to make broad recommendations regarding the industry or legislation. However, in this instance, I believe the above control is adequate and requires no further legislation.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. You conclude your statement by saying, "However, in this instance I believe the above control is adequate and requires no further legislation."

What do you mean by that?

Mr. ROUNDS. This particular test. The one recommended by the Food and Drug Administration seems to be adequate for this particular test.

Mr. KLEINFELD. You are discussing this particular test?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. In connection with the test and shampoo to which you refer—when was that product placed on the market?

Mr. ROUNDS. The current product was placed on the market about November 15.

Mr. KLEINFELD. What year?

Mr. ROUNDS. 1951.

Mr. KLEINFELD. What did you make before November 15, 1951?

Mr. ROUNDS. We made a product under the same trade name that had been on the market for about 4 years.

Mr. KLEINFELD. And it was a dandruff-treatment shampoo?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. What tests did you make on that product before putting it on the market?

Mr. ROUNDS. Well, that product came to us through a wholly owned subsidiary company. It came from Fairfield Laboratories, who are wholly owned subsidiary company.

Mr. KLEINFELD. Wholly owned by you?

Mr. ROUNDS. Yes, sir. I don't know what tests were conducted on their product, except normal and regular reliance on technical data sheets as supplied by manufacturers.

Mr. KLEINFELD. You are president of Fairfield Laboratories?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. And the subsidiary is a subsidiary of Fairfield Laboratories, is it not?

Mr. ROUNDS. It was until it was forced to suspend operation.

Mr. KLEINFELD. And don't you know what that subsidiary was doing?

Mr. ROUNDS. The primary function of that subsidiary was to develop procedures and standards for quaternary ammonium compounds.

Mr. KLEINFELD. I ask you again—before you were putting on the market the dandruff treatment shampoo which preceded the product which you put out on the market on November 15, 1951, what tests, if any, were performed on it? If none were performed, please say so.

Mr. ROUNDS. I can't answer that specifically, because that product was developed by the staff at Rhoads Chemical Co. in charge of the chemical engineering.

Mr. KLEINFELD. How long was it on the market?

Mr. ROUNDS. I believe about 4 years.

Mr. KLEINFELD. And during the 4 years you never took the trouble to find out whether any testing was being conducted to show whether the product was safe?

Mr. ROUNDS. Well, we would rely on technical data sheets as supplied by manufacturers. We always ask for complete technical data.

Mr. KLEINFELD. What do you mean by technical data sheets?

Mr. ROUNDS. All available information on the product.

Mr. KLEINFELD. Such as what?

Mr. ROUNDS. Physical properties, recommendations for use.

Mr. KLEINFELD. Eye tests?

Mr. ROUNDS. No.

Mr. KLEINFELD. Tests by dermatologists?

Mr. ROUNDS. There would be that sort of evidence available in the general literature, yes.

Mr. KLEINFELD. Let's not talk about the general literature. We are talking about your product. If you had substance A and substance B, and you put them together, did you or your subsidiary have any information as to whether that combination might or might not do harm to the person using it?

Mr. ROUNDS. Not information that we developed, no.

Mr. KLEINFELD. So it was put on the market without your knowing whether it might cause any damage to anybody; is that not correct?

Mr. ROUNDS. To my knowledge, yes. But after all, I was relying on a competent technical staff.

Mr. KLEINFELD. Composed of whom?

Mr. ROUNDS. Chief chemist and assistant chemist.

Mr. KLEINFELD. And anybody else?

Mr. ROUNDS. No; that would be it.

Mr. KLEINFIELD. Do you think they are competent to make patch tests and toxicological tests and find out whether any systemic reactions may occur? Or whether damage to eyesight may occur from the use of the product?

Mr. ROUNDS. They wouldn't make dermatological tests, no, or systemic tests. I know they had animals in the Philadelphia plant. They might make key toxicity studies. I know they did on certain compounds because I have records of that.

Mr. KLEINFELD. We are talking about the shampoo.

Mr. ROUNDS. Yes.

Mr. KLEINFELD. They didn't make such tests, did they?

Mr. ROUNDS. I don't believe so.

Mr. KLEINFELD. Does the formula change from time to time, or did it change during the 4 years during which your product was on the market?

Mr. ROUNDS. Yes, some changes were made in the formula.

Mr. KLEINFELD. Were any tests made to establish that the new formulation might not cause some injury to consumers?

Mr. ROUNDS. No, because we had technical information on the products which replaced another product.

Mr. KLEINFELD. I am not an educated chemist. Please tell me what you mean by technical information. What has that to do with safety? We are talking about your product, your shampoo. Were any tests performed on your product when the formula was changed, by any qualified person, in an attempt to establish that it wouldn't hurt anybody?

Mr. ROUNDS. No, because the material that was substituted, one material for the other, varied inconsequentially.

Mr. KLEINFELD. How do you know that it varies inconsequentially? Are you qualified to make such determination?

Mr. ROUNDS. Only by interpreting technical data sheets.

Mr. KLEINFELD. Are you scientifically trained?

Mr. ROUNDS. No.

Mr. KLEINFELD. I have here a report from the Food and Drug Administration on one injury which apparently was caused by the product not mentioned in the statement, the product which you sold before November 15, 1951. This is what is reported to the committee:

A typical eye injury complaint was suffered by Mrs. Dora A. Clark of Los Angeles, Calif. During the time she was washing her hair, some of the shampoo got into her eye. She washed her eyes with tap water as soon as she felt pain. Her eye became swollen and very red. The eye continued to get worse and it was repeatedly washed with a boric acid solution. In the evening an ophthalmic ointment was applied. The following morning a doctor was visited and his diagnosis disclosed a serious injury to approximately three-fourths of the cornea. It was necessary to apply a local anesthetic to the eye to enable Mrs. Clark to sleep. Three days after the injury, Mrs. Clark was still under the doctor's care and there was reason to believe that such care would be necessary for a considerable period of time.

Now, they are talking about your product, are they not here?

Mr. ROUNDS. Yes.

Mr. KLEINFELD. When did you first receive a complaint that such eye injury was being caused to people who were using your shampoo?

Mr. ROUNDS I couldn't say.

The CHAIRMAN. You mean to say that as president of this corporation you don't remember receiving a complaint, you don't remember the time that the first complaint was received?

Mr. ROUNDS. I remember receiving a complaint, but I couldn't name the date of it.

The CHAIRMAN. Approximately. We don't want to know the day and the hour.

Mr. ROUNDS. I would have to refer to my files.

The CHAIRMAN. Would it not come to your attention as the president of the corporation that was selling this product, if you received a complaint?

Mr. ROUNDS. It certainly would.

The CHAIRMAN. Can you tell us approximately the month of the year, whether it was spring, spring of what year, or the fall, or when it was?

Mr. ROUNDS. No, I honestly couldn't.

The CHAIRMAN. All right. Go ahead.

Mr. KLEINFELD. Is it not a fact that when these injuries began to occur the Food and Drug Administration came to you and asked you to recall your product from the market?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. Did you do it?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. How soon after they asked you to recall it did you recall it?

Mr. ROUNDS. The operation stopped at the moment they made the request.

Mr. KLEINFELD. And you sent out wires or letters to your people?

Mr. ROUNDS. We went through a formal recall program, yes, sir.

Mr. KLEINFELD. Isn't it a fact that before the Food and Drug Administration called upon you and asked you to recall your product you received from 15 to 20 eye-injury complaints during a period of 12 to 15 months?

Mr. ROUNDS. I don't know whether that was between a period of 12 to 15 months or during the entire 4 years the product was on the market.

Mr. KLEINFELD. Well, did you receive about 15 to 20 eye-injury complaints?

Mr. ROUNDS. I would say so.

The CHAIRMAN. Wait a second. You say during the entire period on the market. You told us it was on the market for approximately 4 years; is that right?

Mr. ROUNDS. Yes, sir.

The CHAIRMAN. Well, if you received a complaint in the early days and you didn't recall it from the market for 4 years, that would be negligence, would it not, on your part?

Mr. ROUNDS. Oh, no. I am not trying to intimate that there weren't complaints about the product. I just can't tell you when they were.

The CHAIRMAN. All right, go ahead.

Mr. KLEINFELD. There were, within some period of time, about 15 or 20 complaints about eye injuries?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. When you got those complaints did you then immediately withdraw your product from the market?

Mr. ROUNDS. No, we did not.

Mr. KLEINFELD. Why not?

Mr. ROUNDS. We weren't sure what was causing the complaints and whether or not they were complaints that were due to the product being—what the complaints were due to. We just didn't know.

Mr. KLEINFELD. Didn't these people say they had received this eye injury after using your product?

Mr. ROUNDS. That would not answer the question as to whether it might be an allergy or not.

Mr. KLEINFELD. Suppose it was an allergy, and suppose you label it, for the sake of argument, an allergic reaction, does that mean you should not discontinue selling your product? What difference does it make what you call it?

Mr. ROUNDS. I believe it is all a question—after all, the product was being widely distributed. There were probably several million applications, and it would appear that infrequent reports of claims for alleged injury might be a very low incidence. I didn't know how it compares with other cosmetics at all.

Mr. KLEINFELD. You say "alleged injury."

Mr. ROUNDS. In the case of allergy the product might not even have been used by a person.

Mr. KLEINFELD. Did you pay any of these people any money for the injuries they had sustained?

Mr. ROUNDS. Oh, yes.

Mr. KLEINFELD. Then you believed the injuries were caused by your product; did you not?

Mr. ROUNDS. They stated so.

Mr. KLEINFELD. And you paid the complainants; did you not?

Mr. ROUNDS. In the interest of good customer relations; yes, certainly.

Mr. KLEINFELD. What investigation did you perform on your product after the complaints had been received by you?

Mr. ROUNDS. After the Food and Drug Administration——

Mr. KLEINFELD. Oh, no; after you had received complaints from 15 to 20 persons that your product was apparently causing eye injury, did you take the trouble to institute an investigation to determine whether the injury was being caused by your product and what in your product was causing it and how serious it was?

Mr. ROUNDS. We had no indication of what might be causing it.

Mr. KLEINFELD. Did you try to find out?

Mr. ROUNDS. By constant reference to literature; yes.

Mr. KLEINFELD. What do you mean by "literature"? Did you go to the people who had been injured or had been allegedly injured and ask them what happened?

Mr. ROUNDS. No, sir.

Mr. KLEINFELD. Did you go to the Food and Drug Administration and bring the facts to the attention of that agency?

Mr. ROUNDS. No, sir.

Mr. KLEINFELD. You read the literature?

Mr. ROUNDS. Yes. There was nothing in the literature to indicate that the product or compound would be toxic to skin.

Mr. KLEINFELD. Suppose there is nothing in the literature which so indicates but, as a matter of fact, a shampoo such as yours does cause damage, are you going to rely on the literature or on the fact that damage was caused by your product?

Mr. ROUNDS. We would rely on the results from the use of the product.

Mr. KLEINFELD. Did you rely on the results here in withdrawing the product from the market since it did cause injury?

Mr. ROUNDS. Not immediately; no.

Mr. KLEINFELD. Four years after?

Mr. ROUNDS. We didn't have complaints for 4 years; I don't believe.

Mr. KLEINFELD. What period of time?

Mr. ROUNDS. Well, immediately prior to removing the product from the market was when we received the greatest number of complaints, I would say.

Mr. KLEINFELD. What period of time?

Mr. ROUNDS. Immediately prior to removing the product from the market.

Mr. KLEINFELD. At that time you made a formula change, did you not?

Mr. ROUNDS. Yes.

Mr. KLEINFELD. And after that you then recalled your product?

Mr. ROUNDS. Yes, sir.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. You believed in your product, did you not?

Mr. ROUNDS. Yes, sir.

The CHAIRMAN. As soon as you received a complaint, why didn't you immediately go to a laboratory and say, "I want you to test this product and find out whether it could cause the injury complained of." Did you do that?

Mr. ROUNDS. No, we didn't do that, probably because the complaints were so infrequent. And we didn't know what might be causing them.

The CHAIRMAN. All right.

Mr. Abernethy?

Mr. ABERNETHY. Yes; I have one question. When you received the first two or three, let us say, complaints about the product, I understood you to say there were 12 or 15, what did you do about them?

Mr. ROUNDS. We wrote to the customer, who was generally quite a distance from us.

Mr. ABERNETHY. Did you reply to all of them?

Mr. ROUNDS. Pardon?

Mr. ABERNETHY. Did you reply to all the complaints?

Mr. ROUNDS. I believe we did.

Mr. ABERNETHY. Did you differ with them as to what happened or seek additional information from them?

Mr. ROUNDS. We certainly wouldn't differ with them or argue with them.

Mr. ABERNETHY. What did you say?

Mr. ROUNDS. We certainly would send them a letter and tell them if they felt they had suffered some discomfiture resulting from the use of our product we were certainly very sorry, and if they experienced any financial expenditure by virtue of doctors' visits, we would reimburse them for it, which we did.

Mr. ABERNETHY. Well, I don't want to be misunderstood. I just can't believe that anyone putting a product on the market would deliberately continue to process and distribute that particular commodity when he knows it might be causing someone some particular injury. In my judgment, you were a little bit slow and reluctant to take the initiative and do something about it. That is what brings on the hearing we are conducting now and brings on new laws and new supervising agencies, which business does not like.

We as free Americans and free businessmen do not like to have somebody governing our business. But the failure of many of us—sometimes me, perhaps, sometimes you, maybe someone else—to immediately take steps and correct a thing of that kind is what brings governing agencies and controls upon the people.

I really was not too much concerned about this cosmetic subject until we got into it. Now I think it is serious enough that probably something is going to have to be done to bring a little more supervision over the processing and distribution of the products.

That is all, Mr. Chairman.

The CHAIRMAN. Mr. Jones?

Mr. JONES. About how many packages of this shampoo did you distribute under your first formula, the formula you were using before it was recalled?

Mr. ROUNDS. Probably several hundred thousand, I imagine. That is just a guess.

Mr. JONES. What procedure did you use for trying to take that off the market, to recall it, to get it off the shelves after you decided to change the formula—to get the old product off of the market, the one you evidently feel was causing some harm or at least causing complaints?

Mr. ROUNDS. We notified every jobber.

Mr. JONES. Every jobber?

Mr. ROUNDS. Yes, sir.

Mr. JONES. Did you think the jobber would notify the retailer and on down the line?

Mr. ROUNDS. Yes, sir.

Mr. JONES. Did you volunteer to replace any of the old formula with the new formula?

Mr. ROUNDS. We did so; yes, sir.

Mr. JONES. You did do that?

Mr. ROUNDS. Yes, sir.

Mr. JONES. And it is your belief that you used every effort you could to take the product that caused the complaints off the market, and were you satisfied that you had got it all off the market when you put out the new product?

Mr. ROUNDS. Yes, sir.

Mr. JONES. That is all.

The CHAIRMAN. Anything further?

Mr. KLEINFELD. I have nothing further.

The CHAIRMAN. You are excused.
Mr. ROUNDS. Thank you.
The CHAIRMAN. Call the next witness.
Mr. KLEINFELD. Mr. Rheinstrom.
The CHAIRMAN. Your name and address?
Mr. RHEINSTROM. Robert I. Rheinstrom. The address of our office is 745 Fifth Avenue, New York.
(The oath was administered by the chairman.)
I would very much appreciate having Dr. Goldzieher permitted to sit next to me.
The CHAIRMAN. There is no objection.
Mr. RHEINSTROM. Thank you.

TESTIMONY OF ROBERT I. RHEINSTROM, REPRESENTING HIRESTRA LABORATORIES, INC., NEW YORK, N. Y.

Mr. KLEINFELD. Mr. Rheinstrom, what is your position or connection with Hirestra Laboratories?
Mr. RHEINSTROM. I am the founder of Hirestra Laboratories. I built that business up with the aid of the gentleman to my left and a number of others who are mentioned in my paper. So I will save you time and won't repeat that.
Mr. KLEINFELD. What is the name of the gentleman to your left?
Mr. RHEINSTROM. Dr. Goldzieher.
Mr. KLEINFELD. His first name?
Mr. RHEINSTROM. Max. Other men are mentioned here. I built that business up and in 1946 sold it.
Mr. KLEINFELD. What is your present connection with it?
Mr. RHEINSTROM. My present connection with it is advisory.
Mr. KLEINFELD. Advisory?
Mr. RHEINSTROM. Adviser.
Mr. KLEINFELD. Will you please read your statement?
Mr. RHEINSTROM. Hirestra Laboratories, Inc., of 745 Fifth Avenue, New York, N. Y., manufacturer and distributor of the Endocreme line of cosmetic products, by Robert I. Rheinstrom, its founder, respectfully shows to this committee, as follows:
Hirestra Laboratories, Inc., hereinafter referred to as "Hirestra" or "Endocreme" was incorporated in November 1936 after several years had been spent in the research and examination of a new product of a scientific nature that could safely be presented to the public, having as its purpose the benefit to the skin of the user. In the course of the intervening years, Hirestra has adhered to this policy and each of its products has been thoroughly tested before marketing. Of greatest interest, perhaps, to this committee is Hirestra's experience with its Endocreme hormone face cream, its first product and the first successful product of its kind and which has received wide acceptance ever since its introduction to the public in 1937 [coughing]. Excuse me. My throat is a bit off, but I didn't want to delay anything here today.
The CHAIRMAN. Take your time.
Mr. RHEINSTROM. Endocreme hormone face cream contains ingredients which are used in the preparation of the finest face creams and in addition contains a normal hormone—10,000 I. U. per ounce, with a 2-ounce supply for a 30-day use.

Mr. KLEINFELD. Did you mean normal or natural hormone, sir?
Mr. RHEINSTROM. Natural.

The exact ingredients have been listed by Hirestra with various Federal agencies, including Food and Drug Administration, Federal Trade Commission, Pure Food and Drug Division, and Alcohol Division of the Treasury. For business reasons we respectfully prefer not to furnish these at this time for the public record, but they were sent December 29, 1951, to the members of this committee.

Its formula, as originally conceived, has remained substantially unchanged except for very minor ingredients which were added to maintain homogeneity.

Estrogenic hormones were introduced commercially into the United States in the early 1930's by the well-known Schering Corp., of New Jersey. As early as December 1935, Schering's research division, after careful research, determined that the female hormone known as estradiol, then being produced by Schering, was, on application, absorbed through the skin and that when so absorbed, did have a beneficial local effect on tissues under and in the skin, thereby generally improving the tone and texture of the skin where applied.

Dr. Alcan Hirsch, now deceased, a member of that research division and a chemist of high repute, passed this information on to me, the originator of Endocreme and the founder of Hirestra. At that time I had completed a business survey of the cosmetic field and was then in search of an ingredient which would prove to be really beneficial when incorporated as a component part of a new face cream. The idea of introducing the hormone in low potency into a cosmetic face cream was thus born. Dr. Hirsch thereupon joined forces with me to implement the conception and to further test the conceived product which was thereupon named and has ever since been known as "Endocreme."

An arrangement was thereupon made for Schering to supply the natural hormones to Hirestra. Hirestra then spent about 2 years having tests made to determine the efficacy of the new product and to prove its harmlessness. The aid of Dr. Max Goldzieher, who is now before this committee, was thereupon enlisted. He has continued ever since then on the scientific staff of Hirestra. Among other advisers on such staff have been renowned chemists and physicians of note, some of whom have served the Government, including Dr. Samuel M. Peck, Dr. Udall Salmon, Dr. Louis Schwartz, and our highly esteemed Dr. Harvey Seil, now deceased.

Samples were furnished first to Dr. Goldzieher, who tried them on his private patients. Biopsies then made by him of skin to which Endocreme had been so applied clearly demonstrated beneficial results with no evidence of irritation or harm. The testing was thereupon expanded to include tests conducted by Dr. Salmon and his partner, the late Dr. Geist, by the said Dr. Samuel M. Peck, Dr. Louis Schwartz, and by five other doctors—including endocrinologists and dermatologists—all of whom conducted these tests on their private patients. These tests showed a definite improvement of the skin in 70 percent of the cases tested and that such improvement was obtained in from 10 days to 4 months, depending upon the age of the user, and daily application by the user. There was no evidence of harm or systemic effect. The tests were thereupon expanded on a much larger scale on

about 30 patients at Grassland's Hospital, Valhalla, N. Y., and immediately thereafter to 550 women across the country. These expanded tests conducted over a period of about 6 months again conclusively affirmed the results which the above-named doctors had noted as a result of their privately conducted tests. All of these tests, so conducted over a period of at least 2 years, showed no case of harm whatever to any user. In addition, samples of Endocreme were distributed among numerous members of the medical profession of this country, together with literature stating that there was contained in the product estradiol, with the request that such doctors test Endocreme upon their patients. Letters of commendation were received from such physicians, including specialists, certifying to the beneficial use of Endocreme as observed by them, and in no instance making mention of or reporting any harm of any kind to any women who had used it.

After the completion of the afore-mentioned tests and at about the time that Endocreme was being introduced to the public, Dr. Samuel M. Peck and I, at my suggestion, in September of 1937, flew to Chicago and fully informed Dr. Morris Fishbein, the then editor of the Journal of the American Medical Association, concerning Endocreme and the tests which had been made. This visit was occasioned because of the novelty of the product which marked a new era in cosmetics and my desire to properly acquaint the medical profession through the American Medical Association with the product and a description of the tests and the results achieved thereon. We were thanked by Dr. Fishbein, who seemed very favorably impressed who then stated to us:

> As long as you follow the leadership of Dr. Peck, you will have no trouble.

Before ads of the new product were accepted by such prominent magazines as Vogue, Harpers, Woman's Home Companion, Medical Record, Good Housekeeping, and all of the leading newspaper chains of the country, Hirestra presented to their management the results of Hirestra's tests upon Endocreme and convinced management in each instance of the benefits and harmlessness of Endocreme, so that the ads were in all instances accepted.

Despite Dr. Fishbein's assurance, as above, however, the AMA in April 1938, made an unwarranted attack upon Endocreme by an article published in its said journal, edited and sponsored by Dr. Fishbein, and which was captioned: "Endocreme—a cosmetic with a menace." This unwarranted libel of the company and its product provoked litigation which continued from 1938 to 1940, during which time the despositions of physicians on both sides of the controversy was taken. No testimony, however, was adduced from any of such physicians to substantiate that harm had ever been caused by the use of hormones or that the low potency of hormones in cosmetics could have any systematic effect. The evidence further revealed that the atack was based upon tests hurriedly made on rats with a potency of many hundred times normalcy.

Hirestra thereupon, in 1940, presented in written form to Dr. Campbell, the then head of the Food and Drug Administration in Washington, a complete history of the development of Endocreme, the tests which had been made, the charges leveled against it by the AMA in its said attack, and the views of other unprejudiced, highly experi-

enced physicians refuting such attack. Dr. Fishbein and the AMA were invited by Dr. Campbell to submit evidence as against Endocreme. As far as we know none was submitted. Suffice it here to say that after a most thorough and searching investigation on the part of the FDA, Dr. Campbell then stated in 1940 to me: "There is no interference"—and down to the very date of this hearing there has been no interference. We wish also here to note that as recently as 1951, the FDA as part of its follow-up activities in the matter, at our invitation under the direction of Dr. P. B. Dunbar, then in charge, conducted a survey of Hirestra's records and failed to find evidence of even one case of harm over all of the years since 1937.

Over the course of the years, endeavors were made by uninformed persons, from time to time, to persuade the health departments of several States to prohibit the sale of hormone cosmetics without a doctor's prescription first had. In all instances the scientific evidence presented by Hirestra—and by that time developed by other hormone-cream manufacturers—convinced such departments that such limitation on the sale of these products was unwarranted. The most recent instance was the hearing before the Louisiana Board of Health held in 1949. It is interesting to note that after the scientific evidence of the hormone-cream manufacturers was presented by their doctors, the State health authority asked for a recess in order to obtain evidence from the various medical societies of the country to counteract the claims of the manufacturers. Despite the fact that extreme care was taken and a countrywide trip made by members of the Louisiana Medical Society in search of supposed contrary evidence, when the meeting was reconvened a month later, the answer was that the doctors had failed to adduce any evidence which would in any way contradict the evidence submitted by the manufacturers' medical experts.

Endocreme has been on the market for 15 years, during which time millions of jars have been used by thousands and thousands of women. Hirestra's files are replete with thousands of letters from grateful users of the product. Over the course of these years not a single case of harm from the use of Endocreme has ever been proven, nor have we or our products liability carrier ever paid one cent in settlement of any such claim.

As a result of its experience and success with Endocreme, the following items were added by Hirestra to its line: (*a*) Endocreme cleansing cream, a superior cleansing cream containing no hormones. (*b*) Endocreme hand beauty, a hand lotion which contains hormones.

The formulas as to each of these items were developed and approved by the scientific staff of Hirestra and adequate tests were made with the results that, despite their wide public acceptance, there has likewise been not one case of harm. The ingredients contained in these products have been disclosed to the said Federal authorities and to the members of this committee.

In testifying before this committee, we have been given to understand that it is permissible to make suggestions and recommendations. It is Hirestra's view that when a new cosmetic is placed on the market, containing an active therapeutic ingredient, not previously used in cosmetics, that such product should first undergo a series of animal tests for toxicity and idiosyncrasy. Subsequently, if warranted, the product should be further tested on humans under actual conditions

similar to those that would exist when the product is marketed. These results should then be discussed in Washington with the chief of the FDA and his staff members, and their reaction considered prior to the marketing of the preparation. A careful batch control should be kept and laboratory samples periodically examined so as to insure that the product always maintains its standards.

Annexed to this statement and for record purposes and the use of the entire committee is a copy of the informal memo entitled "Hormones in Cosmetics Harmless—Doctor's Proof" dated November 8, 1951, which was sent by me to the two medical members of this committee prior to the commencement of their cross-country trip.

Before concluding, please permit me to hand to the committee a folder which contains articles which have been published relating to the use of hormones in cosmetics, and including the summary article written by Milton A. Lesser in the July 1949 issue of Drug and Cosmetic Industry.

The CHAIRMAN. That will be marked for identification subject to approval.

You may proceed.

Mr. KLEINFELD. Mr. Chairman, Mr. Rheinstrom has also annexed to his statement a copy of an informal memorandum which at one time I think he submitted to some members of the committee. Is it your wish this informal memorandum be made a part of the record?

The CHAIRMAN. We will mark it also for identification subject to approval.

(The documents referred to are as follows:)

HORMONES IN COSMETICS HARMLESS—DOCTOR'S PROOF

(Compiled by R. I. R.)

Memo to medical members of the Select Committee To Investigate the Use of Chemicals in Food Products and Cosmetics, per House Resolution 74, dated January 17, 1951; 447, dated October 8, 1951

The following tells the story in a few words, so that those who are interested can get the basic information in the least amount of time.

The doubt about the safety of the use of hormones in cosmetics was instigated by Dr. Fishbein's article in the Journal of the American Medical Association (April 9, 1938) titled "Endocreme—A Cosmetic With a Menace." This article was mainly based on tests made on mice by Dr. Carl R. Moore, professor at the University of Chicago.

Endocreme was conceived in the early thirties and was not introduced until several years thereafter. During all of that time, tests were made by doctors (on their patients) to definitely prove the benefits to be derived from the use of hormones in a cosmetic. These doctors (practicing physicians—dermatologists and endocrinologists) were, and still are, men of high reputation. Some have served the Federal Government and are still called in matters which concern dematology, endocrinology, and cancer.

After we had thus eliminated all doubts about the new product, and because of our regard for the medical profession, one of these doctors and I flew to Chicago (in the fall of 1937) to inform the AMA concerning the new product. Dr. Fishbein thanked us, and stated that as long as the doctor (who apparently had convinced him) served our company, we would never have trouble with the AMA.

I then proceeded to introduce the product to the public, and much to my amazement, Dr. Fishbein, in the April 9, 1938, issue of the JAMA came out with an article titled "Endocreme—A Cosmetic With a Menace." I immediately wrote and—having presented to him our evidence—asked him for the evidence which warranted this attack. His rough answer was: "Get your own evidence."

Dr. Moore, Chicago University, who (the article stated) made the tests refused to see me, but I insisted. He said the tests were made by his staff but he refused to give me the name or the address of the person in charge, and he also said he did not have the basic information.

I finally located a nurse (Naomi Beck) at a hospital in Connecticut. She made the tests, in Chicago, and she told us all about the tests, viz:

Tests were made on cancerous strains of mice.
The potency was 210 times normalcy.
She was requested to hurry the tests so that the report could be published in the April 9, 1938, issue of the J. A. M. A.

The foregoing gives you the basis for the attack and shows why the attack was unwarranted.

As shown hereinafter the amount of estrogen used in reputed cosmetics (10,000 I. U.'s per ounce—2 ounces a 30-day supply) is one-tenth of the amount necessary to produce a minimum vaginal effect.

Here (briefly stated) is what was said by doctors at the hearings in the suit brought (August 1938) by Hirestra against Dr. Fishbein and the AMA after the attack. The statements marked "DEP" are from depositions made by doctors—at the hearings. Other quotations are as identified. These statements will prove to you that the use of hormones in cosmetics is definitely harmless.

RE MICE

Dr. Leo Loeb (Journal A. M. A., "Glandular Physiology and Therapy," 1935): "Cori then attempted to produce cancer in female mice, belonging to a high-cancer strain and castrated at an early period of life, by the injection of estrogenic hormone at regular intervals over a long period of time. These experiments as well as those continued by him, gave negative results, apparently owing to the use of insufficient doses."

RE HUMANS

Dr. Raphael Kurzrok (Ku. Dep., p. 7): "I have given all sorts of (therapeutic) dosages (to humans). I am personally in favor of large doses. They would vary from 50,000 units up (70 times Endocreme). I would say 50,000 units for me would be a fairly small dose (70 times Endocreme). The largest dose—6,000,000 units over a period of 6 years" (Ku. Dep., p. 10). "I don't think very small dosages are of any (therapeutic) effect one way or the other" (Ku. Dep., p. 108).

Dr. Max Goldzieher (Go. Dep., p. 170–171): "I would add that considerably larger dosages of estrogen than I have mentioned (10.5 to 140 times Endocreme) can be given to a human without causing any harm."

RE RATS VERSUS HUMANS

Dr. Emge (J. A. M. A. 6/1/38): "Such warnings are prone to create the impression that what strictly applies to animal experimentation applies also to man. However, laboratory findings until proved applicable should not be interpreted clinically, but should be viewed strictly in the light of species and strain susceptibilities of the particular animals and tumors studied."

Dr. Goldzieher: "It is scientifically unpardonable if a man does not recognize the fundamental difference between the results of experiments in mice and in other animals. Let alone humans." (Go. Dept., p. 177)

Dr. Kurzrok: "The production of cancer in a rat is one thing. The production of cancer in a mouse is another thing, and the production of cancer in a human is entirely a different story." (Ku. Dep., p. 15.) "The transference of these results to the human is beset with great danger."

The relation of estrogen therapy in the human to carcinogenesis.

Dr. Ephraim Shorr and George N. Papanicolaou: "An analysis of the data (5 years of tests at the Endocrine Clinic of the New York Hospital) leads to the conclusion that no evidence exists that estrogenic hormone, given in physiological (normal) doses has led to the development of carcinoma in man." (Third International Cancer Congress, Atlantic City, September 1939.)

Dr. S. H. Ceist and Dr. U. J. Salmon: "The Effect of Long Continued Estrogen Administration Upon the Uterine and Vaginal Mucosa of the Human Female." (Test period 3 months to 4 years—124 cases (humans)—doses 10,000 I. U. to

150,000 I. U., three times weekly.) (42 to 630 times the strength of Endocreme by inunction) "Biopsies studies revealed that there is apparently a limit to the amount of proliferation which estrogens induce. This proliferation falls within normal limits regardless of the dosage or duration of therapy. When the dosage exceeds a certain level, the endometrium is cast off and the vaginal mucosa sheds the cornified epithelial cells. Both phenomena appear to prevent excessive proliferation. Estrogens do not produce proliferation of the epithelial elements of the uterine and vaginal mucosa which transgresses the normal physiologic limits." (Third International Cancer Congress, Atlantic City, September 1939.)

Dr. Salmon (Sa. Dep., p. 130): "I feel that there is no evidence at present that the administration of estrogens to humans carries even a remote hazard of carcinogenesis."

Dr. Seelig (Se. Dep., p. 697): "I have never heard of a malignant condition developing in the human being as the result of the administration or application of any of the estrogens."

Estrogens have no cumulative effect

Dr. U. J. Salmon (Sa. Dep., p. 126): "Estrogens do not transgress the normal boundaries in spite of continued administration of enormous doses".

Dr. M. A. Goldzieher (Go. Dep., p. 172): "We don't know of any dosage high enough to cause damage in humans."

Question (Go. Dep., p. 238): "Do not estrogens have an accumulation in the body"?

Answer: "I would not say that."

Dr. R. Kurzrok (Ku. Dep., 95): "They don't accumulate in the body to the best of my knowledge." (Dep., p. 170) "No harm has ever been caused to my patients by estrogens."

The foregoing is just a small part of the evidence presented by eminent doctors. As a result the suit ended with an agreement worded as follows: "All matters in controversy having been settled to the satisfaction of both sides, the suit is discontinued."

Directly after that I asked Dr. Campbell (head of the FDA) to examine the item, and I made available to them full details of the tests made in the development of Endocreme. I also presented full details of information gathered in the suit. After several months of examination by the FDA, I went to Washington and Dr. Campbell stated—"We have investigated the product—there is no interference." There has been no interference by them ever since.

Irrespective of all the evidence gathered at the hearings, and notwithstanding the unbiased conclusion of the FDA (after their careful examination), trouble makers still continue their efforts.

These efforts were expressed in a number of States—Kentucky, Virginia, Massachusetts, New York, and Louisiana. In every instance our evidence was submitted and the rulings were withdrawn.

The Louisiana instance (1946) will be of particular interest to you. The Orleans Parish Medical Society requested the Louisiana Board of Health to ban the sale of hormone cosmetics. When the ruling was passed, the leading manufacturers asked for a hearing by the Board of Health. The hearing was granted and attended by many members of the Orleans Parish Medical Society, and the doctors who made the tests for the manufacturers were present and described their tests. The members of the Parish were asked to cross-examine the doctors who represented the manufacturers but only one had anything to say. What he said was to compliment Dr. Goldzieher (who tested Endocreme) for the evidence he presented. Following the hearing, the head of the Louisiana Board of Health wrote a letter to the Parish asking for evidence to warrant continuation of the ban. The board delayed its decision on the matter for about a month to enable the Louisiana doctors to obtain evidence in support of their original complaint. A Nation-wide investigation was made by these doctors, and despite such investigation they could not and did not submit any evidence, and the ruling was withdrawn.

With all of the foregoing evidence and with more than 15 years of use by the public without a case of harm, the FDA was (within the last year) asked to examine the files of a manufacturer and to review the history of the use of hormones in cosmetics. They did this, and their latest form letter, in answer to queries, reads: "We have your letter of March 29 inquiring whether a hormone cream may cause cancer. The cosmetics of this type on the market contain from 10,000 to 20,000 units of estrogenic substances in a month's supply. The directions in most cases specify that a small quantity is applied to the face.

These articles have been widely distributed for approximately 10 years and there have been no reports in medical literature which suggest harmful effects resulting from their application."

There is no doubt, and there never should have been any doubt, that hormones in cosmetics are absorbed through the skin, and rehabilitate the cells and layers under the skin, restoring a more youthful look.

The extent to which Fishbein (in recent years) feels that we can be guided by the FDA is expressed in the following statement made by him at an address years after his attack on hormone creams. He said, "The techniques of investigation of the Food and Drug Administration are much more effective than any other techniques I have mentioned." In this same address in 1946 he said, "The new Drug Act made it impossible to introduce a new drug into circulation, or a new product without first having cleared it through the FDA as to the safety or harmlessness of the product concerned, and as a result we have made a great deal of progress in the introduction of new cosmetics and new therapeutic devices, physical-therapy devices, and other materials of various kinds." Dr. Fishbein, in this speech, has affirmed that we can rely on the conclusions of the FDA.

After thorough investigations by the FDA, no case of harm and no fault having been found by the FDA concerning the use of hormones in cosmetics, and the original fault finder and trouble maker having indicated that we can rely on the FDA, there can be no doubt about the safety and effectiveness of hormones in cosmetics.

Irrespective of all the foregoing evidence, the manufacturers of hormone cosmetics will welcome a meeting with the committee on its return from its cross-country trip.

In view of the foregoing, we trust that the situation is completely clear. Unfortunately rash statements made by unqualified observers, have succeeded in reaching the public via newspapers with a resulting harmful and unwarranted effect to the reputable manufacturers of hormone cremes. We hope, therefore, that discussion of this nature will be confined to the meeting at the conclusion of your trip when we will be able to discuss frankly any questions you or your committee may have.

Respectfully submitted.

HIRESTRA LABORATORIES, INC.,
By ROBERT I. RHEINSTROM.

P. S.—The following statements and articles may be of interest:

Dr. Fishbein's speech to the American Marketing Association, October 8, 1946, page 17, "Mr. Maze, the editor of Good Housekeeping, wants to know if the AMA is a racket. I have a very simple answer. It is a good racket, but not as good as Good Housekeeping."

The following described papers on the subject of hormones in cosmetics may also be of interest to you.

Estrogenic Hormones and Carcinogenesis, Surgery, Gynecology, and Obstetrics, February 1939.

AMA launches new attack on estrogen hormone cosmetics, Drug Trade News, June 18, 1945.

The effects of estrogens on senile skin, Dr. Max Goldzieher, Journal of Gerontology, April 1946.

The hormone cream problem, Dr. E. G. Klarmann, American Perfumer and Essential Oil Review, November 1946.

Says estrogen is especially suited to cosmetic use, Drug and Trade News, May 19, 1947.

Mr. KLEINFELD. Mr. Rheinstrom, when this committee first communicated with you you were asked, among other things, to furnish the committee with the names of all the products which your company manufactured for distribution; is that correct?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. And in your statement to us you stated that in addition to Endocreme you added the items—

Endocreme Cleansing Cream, a superior cleansing cream containing no hormones; Endocreme Hand Beauty, a hand lotion which contains hormones.

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Which indicated you were putting out three products?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. And that you were reluctant to furnish the committee with a list of the ingredients of your products, and we then asked you to furnish that information to us. Is that correct?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. And in furnishing that information to us, you mentioned, in your subsequent letter of December 29, 1951, two other products which had not been mentioned in the original statement.

Mr. RHEINSTROM. That is right.

Mr. KLEINFELD. Endocreme Light Cream and Endocreme Hormone Oil.

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. How is that?

Mr. RHEINSTROM. The three items which I mentioned to you and the basic tests from which developed the hormone oil were made during my ownership of the business. These other items are outgrowths of that and are not in my hands. Now we have here our production manager and our doctor of chemistry in addition to Dr. Goldzieher.

Mr. KLEINFELD. You all collaborated on your statement, did you not?

Mr. RHEINSTROM. Certainly.

Mr. KLEINFELD. So in addition to the three products you mentioned in your original statement, your organization also puts out two other items called Endocreme Light Cream and Endocreme Hormone Oil; is that correct?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Is it not a fact you also put out still other products?

Mr. RHEINSTROM. Hirestra does. Those are new products since my administration.

Mr. KLEINFELD. Mr. Rheinstrom, either you or I may be laboring under a misunderstanding. I assumed you were testifying here on behalf of Hirestra.

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. We asked Hirestra to supply the committee with a listing of all the products Hirestra makes.

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Together with a list of all the ingredients.

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Have you furnished the committee with that information?

Mr. RHEINSTROM. I want you to ask Mr. Hansen, about the additional information.

The CHAIRMAN. What is your name?

Mr. HANSEN. My name is Fred Hansen.

The CHAIRMAN. What is your capacity?

Mr. HANSEN. I am plant manager for Hirestra Laboratories. We have submitted formulas, as I understand it, by Mr. Rheinstrom or our lawyer, Mr. Klein, for Endocreme, Endocreme Light Cream, Endocreme Hormone Oil, and Endocreme Cream and Endocreme Hormone Hand Beauty.

Mr. McDONOUGH. Are you referring to your letter to Mr. Delaney of December 29?

The CHAIRMAN. It is in there, yes.

Mr. McDONOUGH. Is that all?

Mr. HANSEN. I beg pardon, sir. We omitted for some unknown reason to me to send to the committee the ingredients used on items that we produce, a shampoo and the scalp lotion, hormone scalp lotion, for which I have statements here which I will present to the committee.

Mr. KLEINFELD. Do you make a shampoo?

Mr. HANSEN. Yes, sir.

Mr. KLEINFELD. That is not mentioned in your statement.

Mr. HANSEN. Beg pardon?

Mr. KLEINFELD. That is not mentioned in your statement.

Mr. HANSEN. That is not mentioned.

Mr. KLEINFELD. Are there hormones in that shampoo?

Mr. HANSEN. No, sir.

Mr. KLEINFELD. Do you make a hair beauty preparation?

Mr. HANSEN. Yes, sir.

Mr. KLEINFELD. That is not mentioned in the statement.

Mr. HANSEN. That is right.

Mr. KLEINFELD. Are there hormones in that preparation?

Mr. HANSEN. Yes, sir.

Mr. KLEINFELD. You make a scalp conditioner?

Mr. HANSEN. Yes, sir.

Mr. KLEINFELD. That is not mentioned in your statement.

Mr. HANSEN. No hormones. I have data on——

Mr. KLEINFELD. The formula for that?

Mr. HANSEN. Yes, sir.

Mr. KLEINFELD. To get the record clear, is there anything else which Hirestra Laboratories makes which the committee has not been informed of?

Mr. HANSEN. No, sir.

Mr. KLEINFELD. Is that right?

Mr. RHEINSTROM. That is right.

The CHAIRMAN. Do you have the ingredients there?

Mr. HANSEN. Yes, sir.

The CHAIRMAN. Let's have them.

Mr. JONES. Mr. Chairman?

The CHAIRMAN. Yes.

Mr. JONES. Will Mr. Kleinfeld yield?

Mr. KLEINFELD. Yes.

Mr. JONES. I do not think we ever did get Mr. Rheinstrom thoroughly identified with the company. He said he was the founder of the company but didn't give the present relation. Are you interested financially as president or as an officer of the company now?

Mr. RHEINSTROM. No; I am not the president. I am only serving in what might be called an advisory capacity.

Mr. JONES. Do you have stock in the company?

Mr. RHEINSTROM. No; I sold the business in 1946.

Mr. JONES. You have no financial interest in the company?

Mr. RHEINSTROM. No.

Mr. JONES. And you are an adviser on a salary?

Mr. RHEINSTROM. You mean adviser on a salary basis, not a salary they pay somebody else.

Mr. JONES. I mean does the company pay you a salary as an adviser with the company.

Mr. RHEINSTROM. Yes.

Mr. JONES. Is it a stipulated sum or on——

Mr. RHEINSTROM. Yes.

Mr. JONES. All right.

Mr. KLEINFELD. Another thing the committee asked you to furnish was a statement of the testing, Mr. Rheinstrom, which your company had performed on its products. Are you in a position to tell the committee what tests your company performed with its shampoo, for example, before placing it on the market?

Mr. RHEINSTROM. I had nothing to do with the shampoo.

Mr. KLEINFELD. Is there anybody here who can?

Mr. HANSEN. Yes.

The CHAIRMAN. The answer is "Yes." We will take that later.

Mr. KLEINFELD. On page 3 of your statement you talk about tests which were made, and you say the tests showed a definite improvement of the skin in 70 percent of the cases tested and that such improvement was obtained in 10 days to 4 months, depending upon the age of the user.

When you say "definite improvement," you mean in the appearance of the skin?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Is it not a fact that that improvement is a temporary improvement which lasts only so long as the hormone preparation is utilized?

Mr. RHEINSTROM. I could answer, but there is somebody next to me that can answer it better than I can.

Mr. KLEINFELD. Fine.

The CHAIRMAN. Are you able to answer?

Mr. RHEINSTROM. Sir?

The CHAIRMAN. Are you able of your own knowledge to answer that question?

Mr. RHEINSTROM. I can say this: that it improves the texture and the appearance of the skin, which is what has been proved by tests.

Mr. KLEINFELD. Can you state for how long a period of time?

Mr. RHEINSTROM. As I remember, the records showed that the improvement came sometime in 10 days to 2 weeks and sometimes in 4 months. It depends upon the condition of the skin and the way the cream was applied.

Mr. KLEINFELD. Are you able——

Mr. RHEINSTROM. That is with the regularity of appliance.

Mr. KLEINFELD. Are you able, on the basis of your knowledge and position in your company, to state as a fact that the preparation caused a permanent betterment of the appearance of the skin in these women?

Mr. RHEINSTROM. Continued use is required.

Mr. KLEINFELD. You have to continue using it; is that correct?

Mr. RHEINSTROM. Yes, sir.

Mr. KLEINFELD. You mention, Mr. Rheinstrom, your controversy with the American Medical Association. You mentioned an attack made by Dr. Fishbein. Here are several articles from the Journal of the American Medical Association. This one is dated April 9, 1938,

this one is June 16, 1945, and this one April 20, 1940. Are you familiar with those?

Mr. RHEINSTROM. I am particularly familiar with the one of April 9, 1938.

Mr. KLEINFELD. I would like to show them to you, Mr. Chairman, and see whether they should be placed in the record.

The CHAIRMAN. I believe they should be.

Mr. KLEINFELD. I think they ought to be placed in the record in order to give a complete picture.

The CHAIRMAN. All right.

Mr. MCDONOUGH. Have you read the articles?

Mr. KLEINFELD. Yes.

Mr. MCDONOUGH. Are they critical of the product?

Mr. KLEINFELD. Yes. These are fairly old—'38, '40 and '45. They are critical.

The CHAIRMAN. I think the door has been opened here to make them part of the record, and I think the witness quotes Dr. Fishbein, and here are the articles that speak for themselves.

Mr. MCDONOUGH. The only point I was making—in his testimony he referred to one instance where Dr. Fishbein attacked the product, and that was later corrected, and he further stated, "From now on there will be no interference."

Mr. RHEINSTROM. That was Dr. Campbell.

Mr. KLEINFELD. That was Dr. Campbell of the Food and Drug Administration.

Mr. MCDONOUGH. Oh, I see.

Mr. KLEINFELD. These articles, as Mr. Rheinstrom has mentioned, were highly critical of his preparation.

Mr. RHEINSTROM. If I may answer that, I would very much appreciate each one of you reading that from A to Z and then going over what I have said here. I would greatly appreciate that, and I am sure all manufacturers who are in the cosmetic business will appreciate that.

Mr. KLEINFELD. Mr. Chairman, I suggest these be placed in the record.

The CHAIRMAN. They will be made a part of the record.

(The articles referred to are as follows:)

[The Journal of the American Medical Association, Chicago, Ill., Saturday, April 9, 1938]

ENDOCREME—A COSMETIC WITH A MENACE

In current periodicals, especially those directed to women, there have been appearing the advertisements for a product called Endocreme. In some of the latest copy which, incidentally, bears the approval of the Good Housekeeping Bureau, appear the following statements:

"Endocreme contains a counterpart of the natural bodily element which helps account for that pink freshness of a youthful skin. This substance is known to the medical world as es-tra-diol, and Endocreme is the only cosmetic which contains es-tra-diol. It helps replenish the supply of the very substance which your skin may lack!

"Endocreme, therefore, is more than 'just a face cream.' It's an active, vital cosmetic which begins its work with the substructure of the skin. In later life, the skin tends to fall into lines and wrinkles because the tissues underneath the skin sag. When Endocreme firms and tones these underlying tissues, the skin is smoothed out again * * * pores decrease in size * * * and lines begin to disappear."

Not only is the product widely advertised, it is also sold over the counter in many leading department stores, drug stores and beauty shops. For more than a

year this product, manufactured by the Hirestra Laboratories, Inc., of New York, has been offered to the public without a word of warning that it may be a potential menance to health and life. Now, on the basis of available evidence, which the manufacturer should have had before the product was sold openly to the public, The Journal is warranted in warning users of this product that its indiscriminate use may lead to dangerous consequences, that it possesses the potentiality of bringing about serious changes in the genital and reproductive organs of women, that it may induce changes in the breasts, and that there is, in addition to possible disorganization of the menstrual cycle, the potentiality of the production of cancer.

Endocreme is claimed to contain 0.625 milligrams of estradiol per ounce. The purchaser of this preparation is told to apply one-half teaspoonful to the face, neck, arms and hands every night and is cautioned against omitting treatment for a single night if the best results are to be obtained. In one of the early advertisements for this product, the statement is made: "There is no danger of overapplication. The skin absorbs only as much as it needs of the vitalizing hormone contained exclusively in Endocreme, the only hormone of its type which has been scientifically proved to be absorbed by the skin." Of course, it has been known for some time that estrogens may be absorbed from the skin and may thus exert systemic effects.[1] Nevertheless, it is claimed that Endocreme acts on the skin alone and has no effect on internal organs.

From many sources now comes scientific evidence indicating the potentiality for serious harm that lies in the persistent use of the product called Endocreme. At the University of Chicago Prof. Carl R. Moore[2] has been making some experiments which are to be presented before a national scientific organization within a few weeks but which have been made immediately available to The Journal so that this warning might be issued. Samples were purchased from a leading department store in the city of Chicago. The product is available in department stores and drug stores everywhere at the price of $3.50 for a 2-ounce jar.

One-half teaspoonful of the ointment was found to weigh about 1.82 grams; on the basis of the claimed content of estradiol, this quantity of cream represents approximately 0.04 milligrams of estradiol. About one-fifth this dose, 0.372 grams of Endocreme (0.0082 milligrams of estradiol) was rubbed daily on the back of the neck (previously shaved) of spayed female rats, young normal male rats and normal male guinea pigs for periods of from 2 to 21 days. The Chicago investigators found that this amount of Endocreme (1) induces an estrous reaction in castrated female rats in 48 hours, (2) maintains normal uterine weight in such rats, (3) induces growth of mammary glands in normal male guinea pigs, and (4) exerts profound degenerative changes in the testes of normal young rats. They believe that continued application of Endocreme to large areas of skin in normal women may have serious consequences in possible disorganization of the menstrual cycle.

Inunction of an ointment containing a potent steroid may be even more effective in producing systemic effects than parenteral injection; indeed, Moore and his associates have found the former to be the more effective method of administering androgens (closely related chemically to the estrogens) owing apparently to slower absorption and hence better utilization. Zondek[1c] found that a given amount of estrogen inuncted into the skin was as effective in the production of mammary growth as the same amount injected subcutaneously. However, to produce an estrous effect seven times as much was necessary by cutaneous administration. Thus, it may be seen that daily inunction of Endocreme may actually lead to as great a systemic effect, at least with respect to certain organs, as parenteral injection of an equal amount of estrogen.

While the dosage of estradiol used in the experiments cited represents a much larger amount per unit of body weight than that recommended for the human being, one must consider both the enormously larger surface area to which the ointment is applied in women as well as the much longer period of administration. Further, the known proliferative effects of estrogens on tissues with which they come into direct contact in high concentration leads to apprehension as to the probable result should Endocreme be applied regularly to a potentially neoplastic pigmented mole such as occurs frequently in the human skin.

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[1] (*a*) Zondek, Bernard: Folliculin, Klin. Wchnschr. 8: 2229 (Nov. 26) 1929; (*b*) Hormone des Ovariums und des Hypophysenvorderlappens, ed. 2, Vienna, Julius Springer, 1935; (*c*) Perkutane Follikelhormontherapie, Schweiz. med. Wchnschr, 65: 1168 (Dec. 7) 1935.

[2] Moore, C. R.; Lamar, Jule K., and Beck, Naomi: Unpublished observations made available through the courtesy of Dr. Moore.

Lesions of various types and in various organs have been produced in animals through the use of large doses of estrogen over long periods.[3] Among these carcinoma of the breast appears to be the most common, but other tissues may also be affected. Two years ago, Gardner and his co-workers[4] reported the production of sarcoma at the site of injection of an estrogenic preparation and recently these investigators[5] have produced carcinoma of the cervix in mice. In an article in this issue of THE JOURNAL, Drs. Gardner, Allen, Smith, and Strong in the department of anatomy of Yale University, at New Haven, found that a tumor or the cervix of the uterus of large size developed in a mouse receiving estradiol and was successfully transplanted into male and female mice of the same inbred strain. They believe also that smaller growths observed in eighteen other mice which had received this substance are probably precancerous growths or early cancers. Incidentally, the injection of the oil used as a solvent for the estradiol benzoate did not produce any such changes.

Shortly after Endocreme was first launched, a periodical called *Drug and Cosmetic Industry*[6] itself issued the following warning:

"We have published little or nothing on * * * hormones in cosmetics * * * since we are, at least for the present, opposed to the use of these materials in cosmetics. * * * Until knowledge is fuller these products should not be administered indiscriminately and without supervision."

Apparently, even experts in the cosmetic industry had misgivings.

Estrogen, as has already been well established, has definite uses in medicine when properly employed under controlled conditions. Now evidence becomes available that this endocrine principle, like all other potent endocrine substances, is a two-edged sword capable of remarkable achievements when properly used and dangerous when carelessly employed. The continued reckless and indiscriminate use of this substance in a cosmetic cream is certainly unwarranted until it has been proved beyond the shadow of a doubt that the menace clearly established in animals does not likewise prevail in human beings.

[JAMA 128:515 June 16, 1945]

STATUS OF COSMETICS CONTAINING HORMONES

Today cosmetic preparations are advertised to the general public with the claim that they produce favorable changes in the human skin rather than merely alter its appearance. The advertising claims that the use of such cosmetics will remove wrinkles, make the skin more soft and pleasant to observe and change older looking persons to younger appearing, attractive and even glamorous people.

Some promoters incorporate hormones, such as estrogenic hormones. Others use impressive statements about lanolin, carbamide or some so-called special stimulating factor. The end result, regardless of the product and the sales approach, is the same—a useless outlay of considerable sums of money by purchasers who still believe in the development of "miracle" compounds that can be used safely with the assurance that their hopes for beauty and health will be fulfilled.

The public is now offered preparations containing ingredients as potent as hormones, without evaluation by any unbiased body. If the cosmetic preparations containing hormones will do all that is claimed for them, they must contain potent agents. Why then, do none stand accepted by the Council on Pharmacy and Chemistry for inclusion in New and Nonofficial Remedies? Any compound promoted to affect the structure or function of a part of the body such as the skin should be carefully evaluated before it is released for general sale.

Much experimental work has been done on the cancer-producing properties of estrogenic substances. In susceptible animals the administration of estrogens has apparently produced carcinoma, but further observations are necessary to determine all possible effects of long continued use of such substances in the

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[3] The Role of Estrogenic Substance in Tumor Formation, editorial, J. A. M. A. 106:1093 (March 28) 1936.

[4] Gardner, W. W.; Smith, G. M.; Strong, L. C., and Allen, Edgar: Development of Sarcoma in Male Mice Receiving Estrogenic Hormones, Arch. Path. 21:504 (April) 1936.

[5] Gardner, W. W.; Allen, Edgar; Smith, G. M., and Strong, L. C.: Carcinoma of the Cervix of Mice Receiving Estrogens, this issue, p. 1182.

[6] Hormone Creams, reader's question, Drug & Cosmetic Industry 41: 706 (Nov.) 1937.

average human being. Some authorities believe that the injudicious use of estrogen-containing cosmetic preparations may permit sufficient absorption from the skin to upset normal body activities. For example, it has been argued that changes in menstrual rhythm may occur because of the absorbed estrogen affecting the activity of the pituitary gland.

Enormous sums of money are being spent to purchase hormone-containing preparations and yet many authorities in the field of endocrinology have stated time after time that there is no satisfactory evidence which would justify the use of hormone-containing cosmetics for their local effects on the skin. More than one authority has questioned the honesty of manufacturers when claims have been made that the promoted preparations would counteract age changes, wrinkles, and skin blemishes.

Authorities in the field of endocrinology have stated that there is no published and acceptable evidence that age changes and wrinkling are consequences of estrogen deficiency or that estrogen therapy in women who are known to be deficient in ovarian secretion produces changes in the skin; nor is the deficiency of ovarian activity to be compared in importance with skin changes due to exposure, lack of care, malnutrition, and many systemic diseases.

The physician who is asked to give advice to his patients concerning the use of cosmetic preparations containing hormones will ask: What are the local effects, the general effects, and what may follow long continued use? Satisfactory data to support the answers offered by the promoters have not been provided.

Frequently there has been suggested the need for carefully controlled studies when potentially active preparations are placed in commerce. Those who have kept in mind the importance of such studies have developed criteria for their guidance. However, when the scientific literature is searched for evidence concerning the studies made prior to the commercial distribution of cosmetics containing hormones and other substances, for that matter, the lack of convincing data is significant.

The prevention and treatment of disease and allied subjects are fields in which conjectural reasoning must give way to demonstrable facts. All new drugs should be studied in the laboratory and the clinic. The Council on Pharmacy and Chemistry in its consideration of new drugs asks for evidence of safety and for evidence to support the claims. Such evidence should be available for all who are urged to use a drug or other special preparation or to comment on its efficacy. Similarly, scientific facts concerning hormone-containing cosmetics should be generally available. Certainly the Council has not received satisfactory evidence on absorption, sensitivity, systemic effects, local beneficial effect, toxicity, relation of age, physical factors such as illness, and other factors. Until these and other studies have been completed, made public and found reproducible by unbiased investigators, there can be little honest reason to indulge in the promiscuous sale of hormone-containing cosmetics. Perhaps lack of such evidence is one of the reasons why promoters have not presented their preparations for Council consideration. Can financial gain be dominating humanitarian interests? If this is true, then there is no excuse for the widespread use of hormone-containing cosmetics.

[JAMA 114: 1561, April 20, 1940]

Hirestra Laboratories vs. American Medical Association

The Journal published a critical editorial in the issue of April 9, 1938, on "Endocreme," a cosmetic containing the female sex hormone estradiol. On Aug. 18, 1938, the Hirestra Laboratories, Inc., the company which distributed and sold this face cream, filed two suits in the Federal Court at Chicago against the American Medical Association, the editor of The Journal, and others. One of the suits was in equity and asked for an injunction and damages on the theory that the defendants had conspired to injure the business of the plaintiff. The other suit was in law and asked damages of three million dollars on the theory that the defendants had libeled the plaintiff and had conspired to injure and destroy the business of the plaintiff (the Hirestra Laboratories). The suit in equity was referred to a federal Master in Chancery to hear evidence and report, together with his findings of fact, propositions of law and recommendations in the premises. In the proceedings before the Master in Chancery the plaintiff took the depositions of various witnesses throughout the United States and many

witnesses appeared in person. Before the evidence of the plaintiff was concluded before the Master and about the time the lawsuit was to come on for trial before the Federal Court and a jury, the plaintiff decided to dismiss voluntarily both of the suits. Accordingly, an order was entered on April 5, 1940, in both the suits dismissing them without costs to either party. There was no consideration paid and no promise given by the American Medical Association or the other defendants to induce the dismissal of these suits.

Mr. KLEINFELD. Was this suit which you filed against the American Medical Association ever concluded by any judgment of any court?

Mr. RHEINSTROM. It was not concluded by any judgment by any court.

Mr. KLEINFELD. So it could not be said that either you won or the American Medical Association won; is that correct?

Mr. RHEINSTROM. Well, I want you to have the facts, so if you care to find out how that came to a conclusion. I mean you may not want to take the time to talk about that.

Mr. KLEINFELD. I think perhaps we are short of time, but it is a fact that no judgment was entered.

Mr. RHEINSTROM. There was a reason for that conclusion.

The CHAIRMAN. If you will state it briefly, we will take your reason. But briefly.

Mr. RHEINSTROM. The suit went on, as you saw, for a long period of time, and it was costing me a lot of money. We had definite evidence all through that, through the many months that this thing continued, that those tests were unfair tests, and that the conclusion was unwarranted.

Well, the thing was, How are you going to bring that to a conclusion? Well, fortunately, a question was asked of Dr. Fishbein. The question was, as I recall it: "Why was it that Schering, having been the originator of the first actual hormone cream, was never given the seal of approval of the American Medical Association?"

The answer was that as long as—and it also referred to the fact that the seal of approval had been given to Eli Lilly and Parke Davis. Why wasn't it given to Schering?

Fishbein's answer was, according to my recollection, that as long as this suit is in effect the seal of approval will not be given to Schering.

Well, that was the end of that day's hearing, and the next morning I was contacted by Schering and money was offered me, which was very important to me at that time.

Gentlemen, excuse the condition of my voice, please.

And a settlement was made. An offer was made to me by Schering, which led to this conclusion of the suit: That all matters in controversy having been settled to the satisfaction of both sides, the suit is discontinued.

Directly after that I wrote a long paper describing everything that had occurred and showing all the tests made by Dr. Goldzieher and other people and submitted that to Dr. Campbell.

The CHAIRMAN. This case was settled then out of court?

Mr. RHEINSTROM. Yes.

The CHAIRMAN. All right. The next question.

Mr. KLEINFELD. The American Medical Association did not make any payment to you; did it?

Mr. RHEINSTROM. No; but that was offered by Schering.

Mr. KLEINFELD. Nobody on behalf of the American Medical Association?

Mr. RHEINSTROM. I can't say anything about that. I don't know.

The CHAIRMAN. You know very well whether you received a settlement from the American Medical Association or not.

Mr. RHEINSTROM. I do not.

The CHAIRMAN. You don't know?

Mr. RHEINSTROM. No. It is none of my business.

The CHAIRMAN. Wait until we get this straight. You instituted an action against Fishbein and the AMA and others?

Mr. RHEINSTROM. Yes.

The CHAIRMAN. And that case was settled. Did you receive anything in settlement of that case from either one of the litigants?

Mr. RHEINSTROM. I received that from Schering.

The CHAIRMAN. From either one of the litigants?

Mr. RHEINSTROM. No.

The CHAIRMAN. All right.

Mr. RHEINSTROM. But from an institution very much interested.

The CHAIRMAN. Go ahead, Mr. Kleinfeld.

Mr. RHEINSTROM. What went on between them and the AMA I don't know. It is none of my business as long as I got the money and we were able to survive and satisfy the Food and Drug later. We are happy and the industry exists.

The CHAIRMAN. Go ahead.

Mr. KLEINFELD. You said you had discussed the situation in 1940 with Dr. Campbell, then chief of the Food and Drug Administration?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Who said to you, "There is no interference." What actually did he tell you besides just those four words?

Mr. RHEINSTROM. Do you know Dr. Campbell?

Mr. KLEINFELD. I met him once a long time ago.

Mr. RHEINSTROM. Well, he is a man that could say that.

Mr. KLEINFELD. What else did he say? Did he just say, "There is no interference"?

Mr. RHEINSTROM. Maybe it will help you if I tell——

The CHAIRMAN. Please answer the question now.

Mr. RHEINSTROM. That is what I am getting toward.

I walked in there. He asked me, "How long do you think I should have to investigate"?

I said, "As long as you want to satisfy yourself."

Now I went there, he sent for me about 2 months later, and his answer was, "We have investigated. There is no interference."

Mr. KLEINFELD. Didn't he also say to you, as a matter of fact, that there was no actual affirmative proof——

Mr. RHEINSTROM. No, sir.

Mr. KLEINFELD. I didn't finish my statement.

Mr. RHEINSTROM. Excuse me.

Mr. KLEINFELD. Didn't he say to you there was no actual affirmative proof which would disclose that your product was in fact dangerous, but that there was no affirmative proof that it was not dangerous, and that because of the limitations of the law he couldn't very well proceed against your product?

Mr. RHEINSTROM. Mr. Kleinfeld, he said nothing more to me than what I have said to you.

The CHAIRMAN. The answer is, "No, he didn't"?

Mr. RHEINSTROM. That is correct.

Mr. KLEINFELD. Mr. Rheinstrom, I want to find out how many products containing hormones you put out, because from the viewpoint of some that may raise a different problem. You put out Endocreme, which is a face cream; is that right?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. When is that used?

Mr. RHEINSTROM. That is used at night before they go to bed.

Mr. KLEINFELD. How much?

Mr. RHEINSTROM. Some people will use it during the day. Generally it is nearly always at night.

Mr. KLEINFELD. How much hormone does it contain?

Mr. RHEINSTROM. The 30-day supply, which is two ounces, contains 10,000 international units per ounce. That is a total of 20,000 for a 30-day supply.

Mr. KLEINFELD. And that ordinarily is put on before a woman goes to bed?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. You also put out an Endocreme hand beauty which is a hand lotion containing hormones?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. What is that used for?

Mr. RHEINSTROM. For the skin of the hands.

Mr. KLEINFELD. What is the strength of hormones contained in that preparation?

Mr. RHEINSTROM. The same as the other. A 45-day supply, 30,000.

Mr. KLEINFELD. Twenty thousand international units?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. For a 30-day supply?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. And that is applied where—the hands?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Where else?

Mr. RHEINSTROM. They may put it on the neck instead of putting cream there.

Mr. KLEINFELD. That will be used only during the day?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Then you put out an Endocreme hormone oil; is that correct?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Is the strength similar to the other preparations which we have mentioned?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. What is that used for?

Mr. RHEINSTROM. A number of people prefer oil to cream.

Mr. KLEINFELD. That is used instead of cream?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Is it sometimes used during the day?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. So that a woman might be using your hormone cream at night and your hormone oil during the day if she chose to?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. Some, you think, probably do?

Mr. RHEINSTROM. Yes.

Mr. KLEINFELD. What is the Endocreme light cream?
Mr. RHEINSTROM. It's a more rapid absorbing cream.
Mr. KLEINFELD. Does that contain hormones?
Mr. RHEINSTROM. Yes.
Mr. KLEINFELD. In the same strength?
Mr. RHEINSTROM. Yes. Generally for the younger people.
Mr. KLEINFELD. The younger women?
Mr. RHEINSTROM. The younger women.
Mr. KLEINFELD. How young?
Mr. RHEINSTROM. We always recommend over 30—30 and over is the average when a women starts to use a cream.
Mr. KLEINFELD. This light cream is meant for women over 30?
Mr. RHEINSTROM. Yes.
Mr. KLEINFELD. And that is the same strength as the other products?
Mr. RHEINSTROM. Yes.
Mr. KLEINFELD. Then you also put out a hormone hair beauty, is that correct?
Mr. RHEINSTROM. Yes.
Mr. KLEINFELD. What is that used for?
Mr. RHEINSTROM. I will let Dr. Goldzieher answer that.
The CHAIRMAN. The doctor has not been sworn. Neither has Mr. Hansen.
Mr. KLEINFELD. Suppose we swear them.
The CHAIRMAN. What is your name and address?
Dr. GOLDZIEHER. Dr. Max A. Goldzieher, office 104 East Fortieth Street, New York City.
The CHAIRMAN. You may proceed.
(The oath was administered by the chairman.)

TESTIMONY OF MAX A. GOLDZIEHER, M. D., NEW YORK CITY

Mr. KLEINFELD. What is the purpose of the Endocreme Hair Beauty, Doctor?
Dr. GOLDZIEHER. The purpose of that preparation is to supply the female hormone estrogen to the scalp. Supplied to the scalp it prevents the formation of dandruff and retards loss of hair.
The CHAIRMAN. Doctor, do you use any of that? [Laughter.]
Dr. GOLDZIEHER. I made the discovery of these effects of the female hormone about 10 years ago, and I was bald 40 years ago.
Mr. KLEINFELD. Do you recommend that the hair beauty preparation be rubbed into the scalp?
Dr. GOLDZIEHER. Yes, sir.
Mr. KLEINFELD. How often?
Dr. GOLDZIEHER. Daily.
Mr. KLEINFELD. Why do you limit the amount of hormones in your preparations to 20,000 units? That is for a 30-day supply, is that correct?
Dr. GOLDZIEHER. Yes.
Mr. KLEINFELD. Why don't you put more in?
Dr. GOLDZIEHER. For the simple reason that putting more in might bring the amount of hormone utilized by the body of the individual within a range of where in exceptional cases it might do harm. And in order to be conservative I have always urged the manufacturers

of hormone creams not to supply more female hormones to any woman for cosmetic purposes than about sixty to eighty thousand units per month.

Mr. KLEINFELD. To whom do you give that advice?

Dr. GOLDZIEHER. To Mr. Rheinstrom and also to a group of manufacturers of cosmetics who invited me to give them a lecture.

Mr. KLEINFELD. But if a woman walks into a drug store she can buy as much as she wants, can she not?

Dr. GOLDZIEHER. Indeed.

Mr. KLEINFELD. Then apparently there is some danger, in your mind at least, that there may be an abuse.

Dr. GOLDZIEHER. No more than buying aspirin over the counter.

Mr. KLEINFELD. You still are careful enough to limit the amounts to 20,000 units for a 30-day period.

Dr. GOLDZIEHER. Because that is all the manufacturer can do. He cannot prevent the customer to use any preparation, even bicarbonate, in any way harmful to the health. That is impossible.

Mr. KLEINFELD. Can he give the consumer a caution or warning?

Dr. GOLDZIEHER. He can give him a direction—this is a 30-day supply. That is what you should use up in 30 days. To say that it would be dangerous to use more would be leaning back too far and might prevent the customer from using something which might be beneficial for her, because she might get ideas it is not safe to use.

Now I made it specific, gentlemen, that in exceptional cases it might do harm.

Mr. KLEINFELD. If there is even the slightest danger—and you indicate there may be—should not there be some caution statement on your label?

Dr. GOLDZIEHER. I believe it would defeat the purpose, if you call a cosmetic dangerous to the public.

Mr. KLEINFELD. I didn't say to call it dangerous. I asked whether you use any caution statement. Do you use the word "caution" on your labels?

Dr. GOLDZIEHER. No; I don't know whether the word "caution" is used.

Mr. RHEINSTROM. No.

The CHAIRMAN. One at a time.

Dr. GOLDZIEHER. To my knowledge the word "caution" is not used. But I always advised the manufacturers to state that this is the amount to be used within a month's time and no more.

Mr. KLEINFELD. Have you got the exact language of your directions with you?

Mr. RHEINSTROM. Thirty-day supply.

Mr. KLEINFELD. Well, do you think, Doctor, saying "This is a 30-day supply" is any caution at all to the ordinary woman, or is it merely a statement of fact? "This is a 30-day supply."

Mr. RHEINSTROM. May I say at this point that they are not going to put more than that on. It doesn't do them any good.

Mr. KLEINFELD. May they not think it may do them good?

Mr. RHEINSTROM. No; they are not thinking of putting more on because they are limited by the time it takes to absorb what they have put on at the rate of a 30-day supply.

Mr. KLEINFELD. Knowing women as you do, don't you think there are many women who might say, "If half an ounce is good, I will use an ounce"?

Mr. RHEINSTROM. No. It would be absolutely impractical.

Mr. KLEINFELD. Then you don't believe there should be any note of caution whatsoever on your label?

Mr. RHEINSTROM. I had hoped that our evidence, never having had any case of harm, shows that what we say on our label is sufficient.

Mr. KLEINFELD. Let me ask you this: Is it not a fairly recent innovation to put hormones in as many products as now contain hormones?

Mr. RHEINSTROM. That doesn't concern me at all.

Mr. KLEINFELD. Don't you wish to answer the question?

Mr. RHEINSTROM. We are only interested in what we make.

The CHAIRMAN. Answer the question if you can. Just answer "Yes" or "No", "I don't know."

Mr. RHEINSTROM. Will you repeat it, please?

Mr. KLEINFELD. Is it not a fairly recent innovation to place hormones in as many products as now contain them?

Mr. RHEINSTROM. Well, they wouldn't be hormone products if they didn't have hormones in them.

Mr. KLEINFELD. Let me put it another way.

Mr. RHEINSTROM. Please.

Mr. KLEINFELD. Originally you put out a hormone cream called Endocreme; is that correct?

Mr. RHEINSTROM. Yes, sir.

Mr. KLEINFELD. What year was that?

Mr. RHEINSTROM. We introduced that in 1937.

Mr. KLEINFELD. When did you next put out any preparation containing hormones?

Mr. RHEINSTROM. I would say that that was about 1942 or 1943.

Mr. KLEINFELD. Which product was that?

Mr. RHEINSTROM. That was the lotion.

Mr. KLEINFELD. When did you next put out a product containing hormones?

Mr. RHEINSTROM. Well, during my administration we worked with those three products—face cream and the cleansing cream and the lotion.

Mr. KLEINFELD. And when did your organization put out the Hair Beauty containing hormones?

Mr. RHEINSTROM. Since 1946.

Mr. KLEINFELD. So that as the situation stands now, a woman may use a hormone cream at night, perhaps for 6, 8, or 10 hours, and have it on her face, throat, neck for considerable periods of time. Then she may, before going to bed and/or during the daytime, place it on her hands and arms. Is that correct?

Mr. RHEINSTROM. Yes; she may.

Mr. KLEINFELD. She may use a lotion, and she may also use a hair beauty preparation. In other words, she may have it on her body practically 24 hours a day—on her face, her neck, her throat, her arms, her shoulders. Is that correct?

Mr. RHEINSTROM. I am going to ask Dr. Goldzieher to answer that.

Mr. KLEINFELD. Isn't that correct, Doctor?

Dr. GOLDZIEHER. Yes; it is conceivable.

Mr. KLEINFELD. Why use the word "conceivable"? Isn't it quite possible?

Dr. GOLDZIEHER. It is just as conceivable, and not only conceivable but known to me as a fact, that some women take a handful of aspirin

tablets and swallow them down like that [indicating], and saying, "If one aspirin tablet helps, a handful ought to be much better."

Against such foolishness there is no protection. No aspirin manufacturer or other drugs which are sold over the counter puts the warning, "Should not be taken by the handful."

Mr. KLEINFELD. In your opinion, then, the possibility of a woman taking large quantities of aspirin tablets sufficient to hurt her is just the same as the woman taking a little extra hormone preparation; is that right?

Dr. GOLDZIEHER. I think it is greater.

Mr. KLEINFELD. Why would she take a lot of aspirin?

Dr. GOLDZIEHER. Usual foolishness.

Mr. KLEINFELD. And she would not take too much hormones because she is not foolish; is that right?

Dr. GOLDZIEHER. No, because it is more expensive.

Mr. KLEINFELD. But you did say, Doctor, did you not, that you purposely limit the international units of hormones in your preparation?

Dr. GOLDZIEHER. By extreme cautiousness, admitting that only in exceptional cases, not in the normal woman, but in exceptional women who are not normal, could by any chance enough hormone be introduced in the body through the skin to cause some sort of an upset like tenderness of the breasts or disturbance of the menstrual periods. That is as far as it goes, and only in women who are not normal.

Mr. KLEINFELD. You think it would drive away customers to say on the label of your products, "Caution—don't use more than a half ounce at any one time."

Dr. GOLDZIEHER. I am afraid I don't qualify as an expert in business matters. I am merely an endocrinologist.

Mr. KLEINFELD. Refer it to somebody else there. Who could answer that question?

Mr. RHEINSTROM. Mr. Hansen.

The CHAIRMAN. He has not been sworn.

What is your name and address?

Mr. HANSEN. Fred Hansen, 25 Oak Avenue, Lindhurst, N. J.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF FRED H. HANSEN, PLANT MANAGER, HIRESTRA LABORATORIES

Mr. HANSEN. On our direction we specify on our cream jar to use a half a teaspoonful a day, which is the equivalent of a 2-ounce jar would last 30 days, and we also specify normal 30-day supply.

Mr. KLEINFELD. That is all you say?

Mr. HANSEN. Yes.

Mr. KLEINFELD. So in connection with each product which you put out that is the only direction?

Mr. HANSEN. Yes. It varies on the various preparations, but that is on the creams.

Mr. KLEINFELD. Dr. Goldzieher, I know that apparently there is nothing in the medical literature which indicates there have been actual cases of harm done by hormones in cosmetics. At least I am not familiar with any. But are you in a position to say that if a woman uses a hormone preparation on large areas of her body for 24 hours a day——

Mr. McDONOUGH. Day after day.

Mr. KLEINFELD. Day after day, week after week, are you in a position to say, if you had the burden of proof, that that might not cause some damage to some women?

Dr. GOLDZIEHER. I would say that it is possible that if a woman uses hormone cosmetics over a very large surface of her body all the time, and if that woman is not a normal woman but one affected with certain kinds of illnesses, that she may have some untoward reaction, but no permanent harm would ever ensue.

Mr. KLEINFELD. What kind of illnesses might she have that would be affected adversely?

Dr. GOLDZIEHER. Well, a woman whose menstrual performance is either abnormal or shows a variability, or women who have a tendency to react with swelling and tenderness of their breasts at certain times of the month. Anyway, if they would take an excess of hormone creams they may have more pain or discomfort in the breasts and more menstrual disorders than they usually have.

Mr. KLEINFELD. Would you be at all concerned in such a situation if there was some family history of cancer?

Dr. GOLDZIEHER. No, definitely not.

Mr. KLEINFELD. What is the minimum therapeutic dose of estrogen, do you know, Doctor?

Dr. GOLDZIEHER. That is, of course, very hard to say in general, because it depends upon the age and the type of woman and the purpose for which it is given. But if you take the most common case, that of the woman who has gone through the change of life, and for this woman in order not to have any of the symptoms of change of life, the average dose is about 1 milligram or 10,000 international units of estrogen a day, which is 300,000 units per month.

Mr. KLEINFELD. Doctor, at our hearings there was a reference to the latest issue of New and Non-Official Remedies. Are you familiar with that?

Dr. GOLDZIEHER. I don't look much at it.

Mr. KLEINFELD. In the Journal of the American Medical Association of June 20, 1942, the council on pharmacy and chemistry of the American Medical Association officially admitted stilbestrol to New and Non-Official Remedies. In so doing this is what was stated, and I would like to get your opinion on it:

> The contraindications to this substance are similar to those for natural estrogens, namely, familial or personal history of malignancy of the reproductive organs.

Do you agree with that?

Dr. GOLDZIEHER. Would I agree with that?

Mr. KLEINFELD. Yes.

Dr. GOLDZIEHER. It is something which is absolutely unproven, but personally I would not prescribe estrogenic medication to a woman who had been operated on for cancer. Because if I would and she gets a recurrence, I would be blamed. But nobody could prove she got the recurrence because she got stilbestrol and she didn't get it anyway. Therefore, I would abstain. I am not willing to take the risk. But I do not think it has anything to do with it. There is no theoretical basis on which that can be claimed.

I can tell you why. Because all the evidence we have that estrogen hormones have something to do with cancer is that if there is a cancer of certain tissues, like breast or uterus, and then you give estrogen, that may stimulate those tissues and increase the rate of growth. But if the surgeon has removed that tissue, and supposedly he has to remove all of it and kill the rest with X-ray or some other radioactive material, there is nothing there to stimulate, and if the patient gets cancer it is proof the surgeon did not remove everything.

Mr. KLEINFELD. Suppose, before the surgeon enters the picture, the woman has cancer which has not yet been discovered. Would the use of hormones be contraindicated there?

Dr. GOLDZIEHER. The use of hormones in therapeutic doses would be contraindicated, and I am sure such mistakes have happened—that the doctor did not recognize the woman had cancer of the uterus and prescribed estrogen hormones. That would be malpractice, and it happens.

If estrogenic hormone is given in cream form as a cosmetic, the amounts are so small that they could not influence the growth or the rate of speed of cancer development. The amount of estrogen which enters the circulation from cosmetic administration remains within the daily physiological production fluctuations of hormones from the woman's own ovaries.

Mr. KLEINFIELD. Have you conducted any actual clinical tests on animals, using the quantities of estrogen which are contained in these products?

Dr. GOLDZIEHER. Oh, sure.

Mr. KLEINFELD. On large areas of the body for long sustained periods of time?

Dr. GOLDZIEHER. Animal experiments for a long period of time by skin application we have not made.

Mr. KLEINFELD. Have you ever seen warnings on labels of laxatives to the effect "Warning—Do not use laxative if you are suffering from abdominal pains which may be caused by appendicitis?"

Dr. GOLDZIEHER. I suppose there are such ones.

Mr. KLEINFELD. That is all.

The CHAIRMAN. Any questions, Dr. Hedrick?

Dr. HEDRICK. This cream you spoke of being put up in 2-ounce containers, that contains 20,000 international units?

Dr. GOLDZIEHER. That is right.

Dr. HEDRICK. If that is used over a period of a month, so much every day for 30 days, how many international units would that woman get a day in your opinion?

Dr. GOLDZIEHER. According to animal experiments which I have made myself, and there is several confirmatory data in medical literature, the absorption from the skin depends on the kind of material it is incorporated with. It will be at a different rate from lanolin, from other fatty base, from emulsion or from alcoholic solution. But if you take a fatty base like Endocreme, we can see that more than one-seventh of the material applied to the skin is absorbed. So that if you apply 20,000 units over the course of a month you cannot have more than 3,000 units absorbed over the month's time. Moreover that is so if you distribute it very evenly so you don't rub off anything. The fact is that most women don't rub it in carefully and quite a bit of material is rubbed off on the pillow or otherwise. So in actual tests the amount

absorbed per month is probably not higher than 2,000 units per month, which gives you a daily rate of about 60 to 70 units, 60 to 70 international units, which is well within the fluctuations of the woman's daily urine assay of estrogen. If you assay the output in 24-hour lots, you get the fluctuation of that order and greater in normal women.

As a matter of fact, the man has in his urine a little bit more than that.

Mr. KLEINFELD. May I ask one more question based upon what you just asked?

Dr. HEDRICK. Yes, sir.

Mr. KLEINFELD. I have an article entitled "Estrogenic Hormones in Cosmetics" by Dr. E. G. Klarmann. Are you familiar with that?

Dr. GOLDZIEHER. I know him.

Mr. KLEINFELD. In part this is what he says:

> When applied in a cosmetic cream, this hormone potency may be safely regarded as being below the threshold value for any systemic action. Assuming that a 2-ounce jar of hormone cream with a total potency of 20,000 international units is used up over a period of 1 month, the individual daily application would contain 666 international units. It is known, however, that absorption from an externally applied ointment does not take place to the extent of 100 percent; at best, it is not greater than 40 percent, and usually considerably less.

Do you agree or not that there can be an absorption to the extent of 40 percent?

Dr. GOLDZIEHER. Not from a fatty base, only from alcoholic lotion.

Mr. KLEINFELD. To that extent you are disagreeing with Dr. Klarmann?

Dr. GOLDZIEHER. Entirely on the basis of my own studies.

The CHAIRMAN. The committee will stand adjourned until 10 o'clock tomorrow morning.

(Whereupon, at 4:50 p. m. the committee recessed to reconvene Friday, January 11, 1952, at 10 a. m.)

CHEMICALS IN FOODS AND COSMETICS

FRIDAY, JANUARY 11, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS OF FOODS AND COSMETICS,
New York, N. Y.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess., continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 10 a. m., in room 128, United States Court House Building, New York City, N. Y., Hon. James J. Delaney (chairman) presiding.

Present: Representatives Delaney of New York, Abernethy of Mississippi, Jones of Missouri, McDonough of California, and Horan of Washington.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. Let the committee come to order.

Call your first witness, Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Behrman.

The CHAIRMAN. Your name and address, Doctor.

Dr. BEHRMAN. Howard T. Behrman, 2 East Sixty-ninth Street, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF HOWARD T. BEHRMAN, M. D., NEW YORK CITY

Mr. KLEINFELD. Where did you obtain your medical degree, Doctor?

Dr. BEHRMAN. New York University College of Medicine.

Mr. KLEINFELD. What year?

Dr. BEHRMAN. 1938.

Mr. KLEINFELD. Have you practiced medicine since then?

Dr. BEHRMAN. I have.

Mr. KLEINFELD. And have you been specializing in the field of dermatology?

Dr. BEHRMAN. I have.

Mr. KLEINFELD. Since when?

Dr. BEHRMAN. Since 1939.

Mr. KLEINFELD. And you are certified in that field by the American Board of Dermatology and Syphilology?

Dr. BEHRMAN. I am.

Mr. KLEINFELD. And are you a member of the American Academy of Dermatology and Syphilology?

Dr. BEHRMAN. I am.

Mr. KLEINFELD. And are you assistant clinical professor of dermatology and syphilology at New York University College of Medicine?

Dr. BEHRMAN. Yes.

Mr. KLEINFELD. You are a fellow of the American Medical Association?

Dr. BEHRMAN. Right.

Mr. KLEINFELD. Have you published any papers in the field of dermatology in the professional publications?

Dr. BEHRMAN. Approximately 60 to 75.

Mr. KLEINFELD. How many?

Dr. BEHRMAN. Approximately 60 to 75. I am not sure of the exact number.

Mr. KLEINFELD. On subjects related to dermatology?

Dr. BEHRMAN. Related to dermatology as well as several books.

Mr. KLEINFELD. Several books?

Dr. BEHRMAN. Yes.

Mr. KLEINFELD. Will you please read your statement, Doctor?

Dr. BEHRMAN. In accordance with your request, I am submitting a statement concerning cosmetics and the necessity for amending pertinent legislation. As a dermatologist, my interest is primarily in the health and care of the skin. Any consideration of the skin should not be merely skin deep but must take into account many systemic and physiologic processes. Actually, the skin is just as much an organ of the body as the heart, lungs, stomach, and liver and is affected by the improper functioning of other organs just as much as some of these organs may be affected by the improper functioning of the skin. Any drug or cosmetic applied to the skin should be given the same consideration as to its effects on the skin and the rest of the body, as any drug that is taken internally or given by injection. Cosmetics applied to the skin may affect the skin and be effective systemically in a number of ways, such as (1) a primary irritant; (2) a sensitizing agent; and (3) a toxic material by absorption through the skin.

With reference to the question of pretesting of cosmetics before marketing, I believe that legitimate cosmetic manufacturers usually are extremely careful in their formulation of cosmetics and in performing such tests. As a member of the committee on cosmetics of the American Medical Association, I believe that most reputable manufacturers are anxious to cooperate in minimizing the incidence of dermatitis and serious injuries to the public, and observe the precautions necessary in this respect. This committee on cosmetics has formulated various methods, procedures, and tests to be followed in order to minimize the incidence of untoward side effects and, if desired, I can review these before the committee. I should like to add that many small manufacturers are more interested in placing upon the market a product for sale, than in the protection of the users. It is extremely important in my opinion that adequate laws be in effect to protect the public against such illegitimate manufacturers.

From a standpoint of danger to the users, I would say that the following products are primarily responsible for the greater number of instances of cosmetic dermatitis, namely, nail polish, lipstick, depilatories, antiperspirants, wave lotions, hair dyes, and soaps. As a few examples of some of the products which have come to my attention and which have caused cutaneous reactions, I may list the following:

(1) Some years ago, a manufacturer of nail polishes placed upon the market a product known as a base coat. This product was applied to the nails before the final polish was used. Its object was to give greater adherence and longer lasting qualities to the nail polish. In this base coat the manufacturer used a synthetic resin which caused fairly severe allergic manifestations in many women, with loss of the nails and other inconveniences. It is my understanding that the company, prior to placing this product upon the market, made tests which apparently satisfied them as to the innocuous character of the product. This occurrence brings out the fact that testing alone without adequate usage studies is not sufficiently effective in proving the safety of a product.

(2) Cold-wave lotions containing ammonium thioglycolate as the active ingredient, have been in use for a number of years. The medical literature is replete with reports of toxic effects due to this chemical. My personal observations of many individuals in contact with these lotions, and additional studies of their effects on the skin and the systemic organs as well, fail to show any unusual incidence of reactions from these preparations. It is my belief that the careful application of such materials in accordance with advised directions is substantially innocuous.

(3) Many of these preparations, as well as facial creams, powders, and so forth, contain various perfumes. Whereas I would not consider a rare allergic reaction as one which could be foreseen, yet it is important to make sure that the index of reactivity is below a fair accepted value before any product is released for general consumption.

Although this question was not raised in your telegram to me, I should also like to state that there are many cosmetics on the market whose intent is primarily to deceive the users by means of suggestive, obscure, and shrewdly worded advertising. I believe that this is particularly true in the field of hormone creams, hair growers, and the like.

In conclusion, I may state that I know of many specific instances of harm resulting from cosmetics. Yet, with the widespread use of the various types of cosmetics, I am of the opinion that in the main they are more or less innocuous. An allergic reaction in a small percentage of the total users is not necessarily an indication that a product is harmful for general use by the masses. I do believe that the leading cosmetic manufacturers usually exercise care and conduct careful test procedures before putting a preparation on the market. I should like to emphasize that the supervision of such studies by men with training and experience along these lines, namely dermatologists, would certainly minimize the incidence of undesirable reactions and serious side effects.

Mr. KLEINFELD. Dr. Behrman, will you somewhat briefly describe the kind of testing which you believe should be performed on a cosmetic before it is placed on the market?

Dr. BEHRMAN. If you would permit me, I would like to just quote a little from—we have a booklet of the official rules which is put out by the American Medical Association Committee on Cosmetics when a manufacturer wishes to obtain the seal of acceptance of this committee.

The CHAIRMAN. Have you extra copies of those?

Dr. BEHRMAN. I am sorry. I have only this one copy.

The CHAIRMAN. Can you leave it with us?

Dr. BEHRMAN. I will be happy to leave it with you.

Incidentally, this rule book was formulated at the initial meeting of our committee in 1949. At our last meeting, which was on December 7, 1951, there were a few minor changes in this which I will mention briefly in giving this to you.

As I said, if a manufacturer wishes to win the acceptance of our committee in accordance with this pamphlet, he submits his preparation to us. I will just go over the highlights of what the steps are.

The first procedure is to send the qualitative, and wherever possible, the quantitative composition of the cosmetic. This information is held in confidence.

Secondly, suitable procedures for the identification and control of the finished product are supplied to our committee.

Third, therapeutic representations normally are not accepted by this committee, as such representations make the product a drug. It has more or less been the practice of our committee to feel that any cosmetic where therapeutic claims are made, which are usually in the field of hormone creams, or hair growth, or preparations of that type, aren't cosmetics and actually are drugs and as such should come under the purview of the Food and Drug Administration.

Fourth, the advertising of these preparations must conform to the claims or statements that can be proved by information submitted by the manufacturer.

Now the outline of the presentation of the submitted product is as follows: A description of the control procedures that are used to assure a product of the claimed identity, quality, and purity. This includes a complete review of the system in adoption at the particular plant, whereby we have complete knowledge of how the product is formulated, made, who was in charge of checking this, what their background is, and other measures with reference to the type of manufacturing organization.

Secondly, we require a statement of any pharmacologic action that might be expected from any of the ingredients and from the final product.

Third, a report from qualified experts on the value of the product for those uses for which it is recommended, provided it differs from those in common use.

Fourth, a report of toxicologic studies sufficiently complete to establish the safety of the product when put to its intended use.

Now, incorporated in this group are what we would expect to find from a standpoint of pretesting the preparation with patch-testing and usage studies.

Now for patch-test studies we require a figure of at least 200 to a thousand subjects to be regarded as an absolute minimum, depending upon the product.

Secondly, we prefer not just a single patch test, which may be a difficult thing to check. We always feel that the method of paired comparison is preferable. In other words, instead of testing with one ingredient and one site, we prefer the same ingredient be tested in several sites to be sure the reactions will overlap one another and we can see specifically whether or not it was just a local reaction.

Formerly we required a routine 48-hour patch-test procedure. Now, as you are probably aware by this time, the 48-hour patch test which was in usage and is still performed routinely is not an adequate measure of the sensitizing properties of a preparation. Whereas the 48-hour test will bring to light any substance that possesses primary irritating properties, it will not bring to light many preparations that are of a sensitizing nature.

The Food and Drug Administration has recently made a large series of studies along these lines, and they are in the process of formulating more specific advice and suggestions. But at the present stage it is felt that a repetition of these patch-test procedures, using the same site over a period of days and retesting within a week or several weeks, will be much more apt to bring to light substances with weak sensitizing potential.

Now, there are other details about patch tests with which I won't burden you. But just a word or two on usage studies.

It is our feeling that patch-test studies alone are not sufficient to give adequate information as to the safety of the product. We feel that usage studies, or in other words the use of a cosmetic to be tested on a large series of people, will give us far more information than just a simple application of a patch test.

As far as the usage studies, we prefer that a control group of the same subjects used in routine patch-test studies be employed, and that the conditions of actual usage be duplicated on the expected sites of usage for a period of at least 2 to 12 weeks, and preferably for 6 months.

If possible, we prefer to have these experiments done with a controlled application of an old cosmetic which we know is within safe limits, particularly when claims of superiority are offered or when irritation is a possible factor. If possible, the cosmetic should be employed so that a new cosmetic is applied to one side of the body or one side of the face, and the old one to the other side of the face so we have this controlled usage experiment as well.

Now, if no dermatitis occurs as the result of these studies in 200 individuals or more, the product is probably safe.

Following this we suggest that a trial sale be carried out where control or supervision can be maintained over a 6-month period. At least 1,000 units should be sold and watched. There are a few more factors here, but I think in essence that is the procedure our committee suggests when a preparation is submitted for acceptance by the American Medical Association Committee on Cosmetics.

Mr. KLEINFELD. Then, Doctor, as I understand your statement, in your opinion and in the opinion of the Committee on Cosmetics of the American Medical Association, that is the kind of testing which should be done before a cosmetic is placed commercially on the market. Is that correct?

Dr. BEHRMAN. That is correct.

Mr. KLEINFELD. And if that testing is not done, then there is a real possibility of injury to users?

Dr. BEHRMAN. I would say yes, depending upon the type of cosmetic.

Mr. KLEINFELD. Do you know whether most cosmetic manufacturers have submitted their products to the Committee on Cosmetics of the American Medical Association for acceptance?

Dr. BEHRMAN. I would say that we have had a fairly considerable number of concerns that have submitted their products. I can't give you the exact figures, but it is my impression that many of the leaders in the field have.

Mr. KLEINFELD. Would it be a very expensive proposition for a cosmetic manufacturer to perform the tests which the committee on cosmetics suggests?

Dr. BEHRMAN. In general, no. I would have to qualify that by saying that according to our old regulations, if just a routine patch-test series of the standard type had been performed, the expense would have been comparatively minimal. If the new suggestions that the Food and Drug Administration have advanced, which include something such as the repetitive testing of the same subject on at least 10 separate occasions, to be followed within a few weeks by another repeat testing, were followed through and you would multiply the group of people who would have to be tested by the number of times they would have to be exposed to the test procedure, it might run into a fairly considerable amount as far as finances are concerned.

I would say that in general the procedure is certainly not a particularly expensive one and one that any reputable manufacturer should be willing to do for the safety of the users.

Mr. KLEINFELD. In other words, if he doesn't perform those tests he is taking a chance?

Dr. BEHRMAN. That is true.

Mr. KLEINFELD. With respect to what may happen to the consumers. Is that correct?

Dr. BEHRMAN. That is true. And I think to a certain extent I often wonder what happens where there is no actual control by a committee such as ours, which is merely an educational rather than a legislative body. As I understand it, the most reputable manufacturers have something called product insurance by which each new product that they put out is insured by their particular insurance company, and they are not permitted in most instances to put out a product unless the insurance company feels that this is a safe preparation. Accordingly, they have to submit studies and procedures that they have done to comply. And I understand it is checked very carefully in some instances. How many or how large a group I can't say, but it certainly would be a disastrous thing for a concern to put out a cosmetic which might produce a great many reactions, and accordingly a great many lawsuits. I am sure their insurance companies, who are well aware of the dangers and issues in this field, check that phase of it particularly carefully.

Of course, it would be much safer if the public were educated to the fact that the seal of acceptance of a body such as ours would insure the safety of the product, but that again is a question of education in the future.

Mr. KLEINFELD. And yet, as you mentioned in your statement, there have been instances where there has been injury?

Dr. BEHRMAN. Oh, yes; there certainly has.

Mr. KLEINFELD. You mentioned, as many witnesses have mentioned to this committee, the performance of patch tests. They are essential, are they not?

Dr. BEHRMAN. Yes.

Mr. KLEINFELD. Who in your opinion is qualified to perform and read the results obtained from patch tests?

Dr. BEHRMAN. I would say the only people really qualified to read and interpret the results are men who have been trained in dermatology; in other words, a dermatologist.

Mr. KLEINFELD. So that if a product was put out, for example, one containing a coal-tar dye and the label contained the statement, "This may cause irritation to some people. Perform a patch test before using it," would Mrs. Jones or Mrs. Smith be qualified to perform the patch test and read the results?

Dr. BEHRMAN. I would say "No." I know you are referring particularly to the patch tests performed by beauticians and hairdressers before applying a dye or something of that sort.

Mr. KLEINFELD. That is right.

Dr. BEHRMAN. And I would say that although it would be a rather simple thing to train a beautician to apply a test and to see whether or not a reaction occurred within a certain period of time, in the vast majority of instances I would say that they could not have enough understanding, experience or training, to really interpret and qualify the reactions that would occur from such an application. In other words, it would be the borderline cases which they might either disregard or not pay too much consideration to which might eventually lead to trouble.

Mr. KLEINFELD. Dr. Behrman, I think you mentioned cold-wave preparations in your statement.

Dr. BEHRMAN. I did.

Mr. KLEINFELD. Cold-wave lotions.

Dr. BEHRMAN. Yes.

Mr. KLEINFELD. And you said that it is your belief that the careful application of such materials in accordance with advised directions is substantially innocuous.

I think there are references in the medical literature of instances where there has been an almost complete or complete loss of hair in some women who have obtained a cold wave. It that true?

Dr. BEHRMAN. Yes.

Mr. KLEINFELD. How do you explain that, Doctor?

Dr. BEHRMAN. Well, it would be a very difficult thing to explain it specifically. If you are talking about cold-wave lotions which might contain the thioglycolates, if the application were left on for an excessively long period of time, it is conceivable that some local depilatory action may occur. But inasmuch as this has been reported in extremely few instances, I would say I am aware personally of just one report of hair loss following thioglycolate.

Mr. KLEINFELD. For example, I have here an article from Northwest Medicine, October, 1949, with the report by two doctors, John T. Robson and Walter Cameron, entitled "Optic Neuritis From Cold Permanent Wave."

Do you happen to be familiar with that?

Dr. BEHRMAN. I am not familiar with that report, although I am quite familiar with the whole field of cold wave literature.

Mr. KLEINFELD. These doctors concluded in this report:

> It has recently been our privilege to care for two patients suffering from optic neuritis in which no etiologic cause other than the cold process could be demonstrated. So far as we know these are the first to appear in the literature.

Do you think it may be that these various injuries, this optic neuritis and complete or partial loss of hair, may be caused by not following the directions or overdoing the use of the preparation, keeping it on too long, or not performing it in the correct manner? What would be your explanation?

Dr. BEHRMAN. I would say as far as the optic neuritis was concerned, I would certainly want very definite and specific proof of something like that. This is the sort of reaction you would certainly want very well qualified men to check up on and report before accepting it.

I would say the possibility of such an occurrence is extremely remote. And as far as the depilatory effect of cold-wave lotions, I have personally observed over 1,200 people in constant contact with the solutions day and night and saw nothing even approaching that type of thing. And certainly you would expect to find it in people in daily contact with these preparations in their manufacture and elsewhere.

Mr. KLEINFELD. Doctor, you say on page 1:

> It is extremely important that adequate laws be in effect to protect the public against illegitimate manufacturers.

When you say "adequate laws," do you mean a law which, generally speaking, would require that before a cosmetic manufacturer put his product on the market he should submit, as the new drug manufacturer is required by law to do now, to some impartial, perhaps a Government agency, proof that he has tested his materials, perhaps performed the tests which you suggest in the booklet you read to the committee, and show that his product won't cause injury to the consuming public?

Dr. BEHRMAN. I would say that there should certainly be some type of procedure or law or possibly some committee or council or body which would take care of that type of thing.

Now as far as the question of actual legislation and control, inasmuch as we are dealing with a cosmetic rather than a drug—and to my mind the incidence of reactions from them is comparatively low as far as actual danger is concerned, and the question is really more of advertising that is misleading or false. I would say the question of controls is one where—is it going to put a very difficult position on the average manufacturer as far as adherence to a very strict routine which might be extremely expensive? I honestly don't know what the type of procedure would be.

I would say that in view of the fact that my feeling is many of them attempt to follow a very honest and sincere approach as far as protection of the public is concerned, the setting up of very strict controls for the occasional manufacturer who is dishonest or misleading or more concerned in making a sale than protecting the public, I don't feel that the entire group should be penalized. I feel they should be controlled, there should be some sort of education from a public standpoint as to what makes a decent product, and so forth. But in setting up any sort of a control legislation or control body, it would depend entirely on what type of procedure was advocated.

Mr. KLEINFELD. Well, let's discuss the procedure which has been recommended by the committee on cosmetics of the American Medical Association.

Dr. BEHRMAN. Yes.

Mr. KLEINFELD. Your committee believes that the type of testing you indicated should be performed?

Dr. BEHRMAN. Yes.

Mr. KLEINFELD. And that type of testing should be performed before a product is put on the market commercially?

Dr. BEHRMAN. Correct.

Mr. KLEINFELD. And you also believe that if that type of testing as recommended by your committee is not performed before a product is put on the market commercially, there is a danger of injury; is that correct?

Dr. BEHRMAN. That is correct.

Mr. KLEINFELD. So should not each manufacturer do what is specified by the committee on cosmetics before it puts its product on the market?

Dr. BEHRMAN. Absolutely.

Mr. KLEINFELD. You are not going to leave it to the judgment of each individual manufacturer, large or small, to determine whether he has, in fact, performed those tests satisfactorily?

Dr. BEHRMAN. No; I don't think that is a completely safe procedure.

Mr. KLEINFELD. No further questions.

Mr. ABERNETHY. I would like to ask one question.

Dr. Behrman, when the manufacturer of a cosmetic meets the standards of your committee of the American Medical Association, are they then privileged to denote that on the packaged product?

Dr. BEHRMAN. Yes, they are. They are permitted to use the seal of acceptance, which can be stamped on all their products; and they can use it both in their advertising and on their products. The seal says:

Seal of acceptance granted by the Committee on Cosmetics of the American Medical Association.

Mr. ABERNETHY. Suppose the public was educated to that fact. Do you think that would be sufficient to control the processing of these materials?

Dr. BEHRMAN. I certainly do.

Mr. ABERNETHY. Then you don't think it would be necessary under those circumstances to have any Federal agency supervise it?

Dr. BEHRMAN. I would say if the public could be educated to that fact, that the important thing to look for would be the name of the reputable firm and the seal of acceptance by an impartial body such as——

Mr. ABERNETHY. Is that a standard seal?

Dr. BEHRMAN. Yes. It is same type of seal granted by our council on pharmacy and chemistry to foods and drugs which meet with their approval.

Mr. ABERNETHY. That is all.

The CHAIRMAN. Mr. Jones.

Mr. JONES. Does that seal of acceptance—of course it does not carry with it any obligation on the part of the AMA of making any warranty to cover any damage that might result from the use of that product, does it?

Dr. BEHRMAN. No; but I would say it indicates a rather careful study of the product.

Mr. JONES. What I am getting at—in other words, then the American Medical Association would not assume to be responsible if a person would take their product and use it and incur some harm to his body or person. There would be no financial responsibility, would there?

Dr. BEHRMAN. No.

Mr. JONES. What I am getting at is this: Yesterday we had a witness here who talked about a certain product, and it was brought out that while the product if used according to directions might be harmless, if the product were used in excessive quantities, it might prove damaging.

Now your committee of the American Medical Association does not pretend to say, or does it, that a product is harmless even if used not according to the directions?

Dr. BEHRMAN. That is true. Our committee can't—you see, I think whatever controls you would set and whatever type of study or groups you might set up to check or control a product, you would still have an occasional person who would be allergic to some preparation no matter what it were, and you could never guarantee that any product would be completely safe because there would always be a person who would react to something in it.

Mr. JONES. What about this? Of course, we were talking yesterday about these hormone creams, and it was suggested that a person might use them in excess. In other words, instead of using about all that was supposed to be for a 30-day period, someone would use that bottle up in a week instead of a month. Would your association or committee propose to put their seal of approval on a product that would be safe, in their opinion, if used according to directions and which might not be safe if it were used in excess and not according to directions? Would you put a seal of approval on a product like that?

Dr. BEHRMAN. I would have to answer that with a little qualification in this respect: It is more or less our feeling that hormone creams are not actually cosmetics but are rather classified under the term of a drug, inasmuch as the claim of the hormone cream is to effect certain changes in the skin which would more aptly be classified as therapeutic rather than cosmetic. The manufacturers claim that these preparations can produce a certain amount of fluid within the connective tissue under the skin as well as changes in the top layer of the skin resulting in proliferation of the surface lining of the epidermis. These changes are actually more therapeutic than they are cosmetic, and as far as hormone creams are concerned, we have never accepted products of that type.

Now, of course, where you take cosmetics which might essentially be safe—and I am not saying that hormone creams are—which might be essentially safe, to get back to your question, when used for a certain period of time—as you say, the manufacturers advise a 30-day period for usage of a certain amount, and where that amount would be used much more quickly and over larger areas than recommended, there are other things which could happen. And——

Mr. JONES. Let's get down to the case of something that you have put the stamp of approval on or permit to use your seal. Take a deodorant, antiperspirant, or something like that. Have you ever put your seal of approval on products of that nature?

Dr. BEHRMAN. Yes.

Mr. JONES. Well, would there be any harm done, in your opinion, if a person would, say, take an antiperspirant and saturate their whole body and do that over a long period?

Dr. BEHRMAN. You would certainly expect any active antiperspirant, such as aluminum salts, if used that frequently and that often you would certainly increase the incidence of reaction to it.

Mr. JONES. And use it over the whole body rather than in certain localized areas, would harm come from that?

Dr. BEHRMAN. Very possible.

Mr. JONES. You still would put a stamp of approval on some of those things if used according to directions?

Dr. BEHRMAN. Yes.

Mr. JONES. What I am trying to get is what precaution a law should take, or how far should we try to go in protecting the public, if we should take any precaution at all, and how closely should we expect the user to follow the directions.

Do you feel there is an obligation upon the person who buys the product to follow the directions?

Dr. BEHRMAN. I would say so, just in the same way in prescribing a drug or even something that would be sold over the counter. If the average person would take a pill for relief of something, and at the same time another person might take 10 or 15 of them, you are bound to get into some type of trouble, and it depends really on the intelligence of the user. Of course, the average person should know in using something of any type where there is a caution label they should read it.

Mr. JONES. Would it be necessary, say, to put a caution label on an antiperspirant to keep a person from using it excessively, or should you just put on there the directions how it should be used and that would be sufficient?

Dr. BEHRMAN. I would say you would have to classify the type of preparation; that there are many of them which could be used—I am talking about things like ordinary face powder, cold creams, and so forth, which you could apply to the entire body as often as you wished without harm. But with preparations where there is possibility of irritation or danger or harm from overusage, the question does arise whether a caution label or direction finder of some type should be put on there in fairly large letters, saying, "Use according to direction," depending upon the type of product. Cold-wave lotions and dyeing preparations all have caution labels to keep people from getting it in their eyes or using for a longer period of time. I think most preparations with potential danger are so worded.

I think in border-line instances the question of adding a caution label is one that should be considered.

Mr. HORAN. I am interested in this American Medical Association approval label. Just how do you check all this? Do you maintain a laboratory some place?

Dr. BEHRMAN. Yes; we do. We have a large one.

Mr. HORAN. Where is it located?

Dr. BEHRMAN. The AMA Building in Chicago.

Mr. HORAN. How many employees do you have there?

Dr. BEHRMAN. I honestly can't answer that.

Mr. HORAN. You do maintain a laboratory to check?

Dr. BEHRMAN. A rather large laboratory. Not only do we have a laboratory from the standpoint of control of cosmetic, but every drug and chemical that is submitted for approval to the AMA. We have a very large laboratory to check all of those.

Mr. HORAN. What does Public Health Service and the Food and Drug Administration do? Do they check your laboratory or is any certification existing there?

Dr. BEHRMAN. I frankly don't know the answer to that. But, for example, on our committee on cosmetics one of our members is the Chief of Pharmacology of the Food and Drug Administration, and we usually have an interlapping association. I would say on most of our committees, such as the Council of Pharmacy and Chemistry, at least one or several members are from the appropriate Government agencies interested in similar preparations.

Mr. HORAN. The point I am getting at is, This is a fine thing in my opinion, but, of course like all fine things, I want to know whether it will stand up in court if something happens? And that is just what my colleague has been asking.

Dr. BEHRMAN. In many instances, in answer to that, where we found some preparation not only not acceptable but dangerous, there would be immediate publication, or if we thought the advertising was misleading or obscure there would be immediate publication or statement to that effect in the Journal of the American Medical Association and all its subsidiary publications such as Today's Health, which is a lay publication, as well as press releases to the newspapers.

Mr. HORAN. You are a very good witness. There is one other question I do want to ask, Mr. Chairman.

What is the objection or what is the trouble that might be involved in, for instance, requiring the basic chemicals in a cosmetic to be placed on the label?

Dr. BEHRMAN. I would certainly say there is no particular objection. I would say that the only objection might come from the manufacturer who might feel he would be disclosing a trade secret. But certainly from the standpoint of the average person or the average doctor, there would be no objection, or they would probably even prefer such a thing.

Mr. HORAN. Thank you.

The CHAIRMAN. Who would the AMA be responsible to?

Dr. BEHRMAN. You mean from a standpoint——

The CHAIRMAN. From any standpoint.

Dr. BEHRMAN. I can't answer that.

The CHAIRMAN. We might just as well have an American stock association to pass on, say, stock that is sold on the market everyday or one to pass on clothing, an American clothing association, or an American washing machine association, or anyone else. We might even have an American election association to pass on elections and candidates.

I mean you are responsible to no one, is that not right, except your own group?

Dr. BEHRMAN. I would say the American Medical Association has been responsible to the people for many years.

The CHAIRMAN. Has been. That is not the question. But there is delegation of power here. Do you think the American public is ready

to accept an independent association that is responsible to no one passing on these cosmetics?

Dr. BEHRMAN. This independent association actually is comprised of doctors, all the doctors of this country.

The CHAIRMAN. Admitting all that, and admitting their ability and so forth, do you think there should be that delegation of power to any group?

Dr. BEHRMAN. I think they are the best qualified.

The CHAIRMAN. There is no question about that. A group of responsible financial men are probably just as qualified to pass upon good stocks and bad stocks, and a group of men who are engineers might pass on automobiles, and therefore you have an American automobile association. Don't you see the possible danger in this?

Mr. ABERNETHY. Mr. Chairman?

The CHAIRMAN. Yes.

Mr. ABERNETHY. I think maybe you misinterpreted what the witness has in mind. I do not think the witness has in mind that there should not necessarily be a Federal agency. As I understand it, this is simply a service which the AMA renders gratis to manufacturers.

The CHAIRMAN. Don't you see the possibility of a growth——

Mr. ABERNETHY. There is no power.

The CHAIRMAN. Definitely no power. There could not be any power. That is why I asked to whom they were responsible.

Dr. BEHRMAN. I would say in answer——

The CHAIRMAN. It is a self-governing group. Is that right?

Dr. BEHRMAN. It is a self-governing group whose responsibility always has been the public.

The CHAIRMAN. And they are trying to help the public, to guide the public.

Dr. BEHRMAN. Yes.

Mr. HORAN. Would you yield, Mr. Chairman?

The CHAIRMAN. Yes.

Mr. HORAN. The reason I asked about the association of your laboratory in this effort—which I think is commendable—the association you have with those bodies who are responsible in this field, namely, the Food and Drug Administration and the Public Health Service, I believe that we would have a little more light on this subject right now if we knew what the association was. It may be true there is a connection there and I would like to know. You yourself do not know and you have so testified.

Dr. BEHRMAN. I can only say——

Mr. HORAN. That would be the check I think we all want, Mr. Chairman.

Mr. ABERNETHY. As I understand, from what the witness says, this particular body which he says is established with a laboratory in Chicago is strictly an advisory agency established by them and maintained out of their pocket for the benefit of the manufacturers and the public. Is that not it?

Dr. BEHRMAN. That is correct.

Mr. ABERNETHY. And if it is worth anything to the public, you want them to have it. If it is not worth anything to them, they do not have to use it.

Dr. BEHRMAN. This is strictly a public service for which there is no charge whatsoever made on any side.

The CHAIRMAN. Any further questions?

Mr. HORAN. I think we ought to know more about the relationship of this laboratory, because it may not be official, but certainly it exists. You know that. I wish someone could elucidate as to what informal recognition there is on the part of responsible parties.

Now we recognize the Government has a certain amount of authority in this country and in this field. It operates with the Food and Drug Administration, and here is your group operating in the same field trying to recommend certain cosmetic and other products before they are sold.

Dr. BEHRMAN. I would say that it certainly could be said in any committee or any specialized council such as this, that there are always one or several members from responsible Government agencies.

For example, I mentioned that the head of the Division of Pharmacology of the Food and Drug Administration is one of the seven members of our committee. And usually our laboratories and our procedures and all our ideas are very similar. I mean, we work them out jointly. That is the reason for always having members of this type on our committee, so that our procedures are actually a check on the same sort of set-up, say, the Food and Drug Administration has, with several advantages. One is that we can—I mean if we find that something has come out on the market which is unsafe or dangerous, we can immediately come out with a statement in publications and so forth, which the comparable agency in the Government cannot do.

The CHAIRMAN. There is no dispute about what you could do. Suppose you grew to such power and recognition that the American public would not accept anything unless it had an AMA stamp on it or no merchant who sold these goods at retail would sell anything unless it had an AMA stamp. Wouldn't that be a great delegation of power?

Dr. BEHRMAN. Yes.

The CHAIRMAN. Great power.

Dr. BEHRMAN. Yes.

The CHAIRMAN. And this group would be responsible to no one. Our Government is sometimes cumbersome, is it not, because we have a check and a recheck. But I am talking about this delegation of power. The only reason we are sitting here is that we must eventually recommend legislation or accept the law as it is. Now if the American Medical Association wants to pass on it, that is only one phase. Why not a group of stockbrokers or a group of mechanical men or a group of clothing men or a group of anything else?

Dr. BEHRMAN. Of course, it is our feeling that the Food and Drug Administration as well as the Federal Trade Commission has certainly legislative power and can act on these things, whereas we are primarily an educational body. There is still enough legislative control and that is certainly under Government supervision. I mean, we are just performing these measures as a public service in the interest of the public health, and we feel we can certainly achieve a certain amount of it from the standpoint of the protection of the public and the public health.

Where it gets to a stage where danger and damage of various types may occur, we feel there are still appropriate Government agencies

and bodies, both locally and nationally, local boards of health and groups like that, who will always act on these measures or who will frequently act independently.

The CHAIRMAN. That is the crux of what we are trying to do now.

Mr. HORAN. Would it be too far afield to ask this question—you mentioned the Federal Trade Commission.

Dr. BEHRMAN. Yes.

Mr. HORAN. I know one cosmetic manufacturer who puts out a whole flock of creams for the skin, one that you use under your chin and another one back of your head, about four or five of them. Is that authentic that certain creams are more effective on certain parts of the body?

Dr. BEHRMAN. That is a highly questionable point. We feel in general most creams, particularly of the cold cream type, have a more or less similar composition and function over most parts of the anatomy, and that such selectivity has very little application from the standpoint of anatomy and physiology.

Mr. HORAN. Then the manufacturer has an ethical responsibility in his advertising, because he is dealing with the most susceptible trait in human nature, and that is vanity. Is that not true?

Dr. BEHRMAN. I would agree with that.

Mr. HORAN. That is all.

The CHAIRMAN. That is all.

Mr. KLEINFELD. Thank you, Doctor.

Dr. BEHRMAN. Thank you.

The CHAIRMAN. The next witness.

Mr. KLEINFELD. Dr. Baer.

The CHAIRMAN. Your name and address?

Dr. BAER. Rudolf L. Baer, 962 Park Avenue, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF RUDOLF L. BAER, M. D., NEW YORK CITY

Mr. KLEINFELD. I am sorry to have kept you waiting, Dr. Baer. Where did you obtain your medical degree?

Dr. BAER. Basle, Switzerland, 1934.

Mr. KLEINFELD. Have you practiced medicine since then?

Dr. BAER. Yes.

Mr. KLEINFELD. How long have you specialized in the field of dermatology?

Dr. BAER. Since 1935.

Mr. KLEINFELD. You are a fellow of the American Medical Association?

Dr. BAER. Yes.

Mr. KLEINFELD. And you are certified in that field as a specialist by the American Board of Dermatology and Syphilology?

Dr. BAER. Yes.

Mr. KLEINFELD. Are you a member of the American College of Dermatology and Syphilology?

Dr. BAER. Yes.

Mr. KLEINFELD. And of the American College of Allergists?

Dr. BAER. Right.

Mr. KLEINFELD. And of the American Psychosomatic Society?

Dr. BAER. Right.

Mr. KLEINFELD. Are you assistant professor of dermatology at New York University Bellevue Medical Center, Bellevue Medical School?

Dr. BAER. Associate professor of clinical dermatology and syphilology.

Mr. KLEINFELD. Associate professor?

Dr. BAER. Yes.

Mr. KLEINFELD. Have you contributed papers in the field of dermatology to medical and other professional publications?

Dr. BAER. Yes.

Mr. KLEINFELD. About how many would you say?

Dr. BAER. Sixty or seventy.

Mr. KLEINFELD. Sixty or seventy?

Dr. BAER. Right.

Mr. KLEINFELD. Please read your statement.

Dr. BAER. For many years Federal laws have made provisions for adequate protection of the consumer's health against avoidable damage from new drugs. This protection has been achieved by making it obligatory that certain clinical and toxicologic data, indicating the relative safety of the drug, are submitted before it is made generally available.

While the law also attempts to protect the consumer against injury from new cosmetics, its provisions with respect to these have been less strict than those pertaining to drugs. It must be stated that serious harm from cosmetics, which might have been avoided under different Federal regulations, has not been a frequent occurrence despite their extremely widespread use. However, it seems reasonable to demand that the law protect the consumer, insofar as possible, against the harmful and dangerous effects of cosmetics, which after all, are not essential to the maintenance of health, at least to the same degree as it protects him against the harmful effects of drugs.

An ideal law would be one which would prevent all harmful effects of cosmetics. Unfortunately this ideal cannot be achieved because even the most basically innocuous cosmetic can in rare instances cause allergic sensitization and under such circumstances it may have a more or less seriously harmful action. As a matter of fact, it should be noted that consumers seem to be willing to take their chances on being harmed by certain cosmetics which produce an altogether not negligible incidence of allergic reactions. Because some possibility exists of allergic reactions from almost any cosmetic it becomes understandable that it is difficult to draw a sharp line in all instances between that incidence which is still acceptable and which is prohibitive. Nevertheless, with the help of common sense it is feasible to come to a decision for each type of cosmetic as to where the incidence of side effects exceeds a justifiable calculated risk.

Most of those interested in this problem will agree that there are some substances or combinations of substances which in the past have been contained in cosmetics and which we know today because of their prohibitively injurious effects should and could have been excluded from such use if the proper precautions had been taken under a law requiring adequate information about their effects before they were sold to the consumer. With the rapid scientific and technical

developments of our time it is likely that other substances will be developed which, from the technical viewpoint, might be desirable ingredients for cosmetics, but which should be excluded from such use or at least from certain cosmetic uses because of their injurious action on the consumer's health. Among the harmful effects are allergic and nonallergic irritations of the skin, irritations of the skin when use of the cosmetic is followed by exposure to sunlight, as well as toxic and other harmful actions on various other organs when some substances contained in cosmetics are absorbed through the skin.

In view of these considerations I favor the following measures to achieve increased protection for the users of new cosmetics:

(*a*) The Food and Drug Administration with the help of the cosmetic industry should draw up and make available a list of compounds which in the past have been and at present are being used in cosmetics without prohibitive harmful effects having been reported. With some compounds it will be necessary to qualify in what concentration and in what type of cosmetic their use is permissible. New compounds for which adequate evidence of innocuousness has been submitted could then be added to this list from time to time.

(*b*) In order to provide a greater degree of likelihood that new cosmetics which are offered for sale do not possess the objectionable properties mentioned above or other potentially harmful properties, the law should be amended so as to make it obligatory that cosmetics which either contain new ingredients or which contain entirely new combinations of previously used ingredients shall be submitted to the Food and Drug Administration for approval before they are released for sale, together with evidence that the new cosmetic does not possess other harmful properties which are detectable by the best testing method available at that time. The Food and Drug Administration should be given some discretion in determining what constitutes an entirely new combination of previously used ingredients.

I now wish to add a few remarks as to what evidence should be submitted to demonstrate the relative innocuousness of a new cosmetic, While valuable as crude screening procedures, the results of skin testing, including patch testing, which are being used for detecting harmful effects of cosmetics on the skin should not be relied upon exclusively as evidence of innocuousness of a new cosmetic. Apart from the fact that such skin tests can only help to discover certain of the side effects in which we are interested here, they obviously cannot reproduce the actual conditions of use and of exposure to the cosmetic. Moreover, a skin test with a cosmetic on one area of glabrous skin does not necessarily indicate what the effects would be on the nail, the tissues under the nail, the eyes and even on particularly sensitive skin areas such as the eyelids, et cetera.

Therefore, every cosmetic which is new in the sense specified above, in addition to being screened through skin tests, should be tested for a period of at least 1 month in volunteer subjects under actual conditions of its proposed use. A certain number of these subjects should be examined by qualified physicians before and after such usage test. Here again it might be well to give the Food and Drug Administration some discretion in determining for the various types of cosmetic preparations submitted, the number of subjects to be included in such usage tests, and the number of subjects who should be examined by physicians before and after the usage test. The standards of desirable

minimum requirements for testing new cosmetics should be worked out by the Food and Drug Administration with the collaboration of representative dermatological organizations such as the American Academy of Dermatology and Syphilology and the Society for Investigative Dermatology.

From what I have stated here it can be concluded that the law can be amended so as to further minimize the likelihood of harmful effects from new cosmetics. At the same time it must be stressed that absolute assurances for harmlessness of a cosmetic product cannot be brought by the methods of skin testing and of limited usage testing available at present.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Baer, on page 2 of your statement you say:

> A skin test with a cosmetic on one area of glabrous skin does not necessarily indicate what the effects would be on the nail, the tissues under the nail, the eyes and even on particularly sensitive skin areas such as the eyelids, et cetera.

In other words, I think you are saying, are you not, that if a cosmetic is to be placed on the commercial market the manufacturer or distributor should take into consideration the use to which it is to be put and the areas of the body on which it may be applied?

Dr. BAER. Yes.

Mr. KLEINFELD. For example, suppose I were to put a new shampoo on the market tomorrow, in determining what tests should be utilized in order to protect the public, before it is placed on the market, would it be a safe precaution in your opinion to determine what effect that hair shampoo might have on the eyes, or the eyelids, and the general orbital area in addition to the scalp and hair?

Dr. BAER. Yes. And I think this can best be done by the usage test, because it is obvious that if the shampoo is used under actual conditions by many hundreds of volunteer users that some of them are likely to get some of the shampoo on the eyelids and in the eyes. And in this way you have a better test than could be done with any artificially designed method. As a matter of fact, it is well known that most cosmetics used on the scalp, if their harmful effects are based on an allergic mechanism, produce a rash as a rule not on the scalp but on the face, neck, ears, and other adjoining areas of the body.

Mr. KLEINFELD. In performing these patch-tests, who do you think should perform those tests and who are qualified to judge the results obtained from such tests?

Dr. BAER. I believe that qualified dermatologists and qualified allergists are capable of evaluating these tests and appraising them properly.

Mr. KLEINFELD. How about the use test? Who should perform such tests and who should be in a position to make a sound judgment of the results of such use tests?

Dr. BAER. I think that qualified dermatologists are the ones who can properly perform and supervise these usage tests.

Mr. KLEINFELD. Then you don't think that an ordinary layman who is not a physician is qualified by training to do so?

Dr. BAER. No.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Mr. Jones?

Mr. JONES. No questions.

The CHAIRMAN. Mr. Horan?

Mr. HORAN. I want to again refer to the difficulty we might run into when you say that qualified dermatologists should be recognized as able to make these tests.

Now I don't disagree with that, but supposing we ran into trouble later on, on what would we base judgment for reprisal of any kind?

Dr. BAER. I do not know what sort of reprisal you are referring to.

Mr. HORAN. Supposing a qualified dermatologist passed on this and it being a matter of judgment, said it was O. K. to go on the market, and it was put on the market and an injury occurred and you had a case in court. You would be left hanging in midair, as our chairman tried to point out a while back, unless we understand what you mean by qualified dermatologists and how they are going to certify to the legality of qualified dermatologists passing on any product. So that later on if injury occurred and the case was in court we would have something to go back to. Because right now we wouldn't have a thing to go back to.

(Discussion off the record.)

Mr. HORAN. The other thing I want to ask you and then I will be through—you indicated that you feel that some amendments to the present law should be had. We want it to be the proper kind of amendment, not burdensome but beneficial. How would you amend the law now, just briefly?

Dr. BAER. In principle I would amend the law so as to subject the sale of new cosmetics to the same regulations that at the present time go for the sale of drugs. That is the principle of the thing. Of course, there are certain differences.

Mr. HORAN. Would you have any objection to having the basic ingredients and the formula placed on the label?

Dr. BAER. I would have no objection, but I think if one does that, one must realize that in some people the ingredients which usually are considered inert, for instance, the basic ingredients in which the colors or perfumes or whatever it is are suspended, can themselves cause reactions in occasional instances. For instance, lanolin and petrolatum or even mineral oil generally are considered innocuous but certainly do cause reaction in an occasional individual.

Mr. HORAN. That is all.

Mr. KLEINFELD. Dr. Baer, from the viewpoint of a dermatologist, do you know of any reason why the same precautions should not be taken with respect to soaps as are taken with other cosmetics?

Dr. BAER. I see no reason why they should not be taken.

Mr. KLEINFELD. The same problem exists there as in regard to cosmetics; is that correct?

Dr. BAER. Right.

Mr. KLEINFELD. No other questions.

The CHAIRMAN. Thank you, Doctor.

Dr. BAER. Thank you.

The CHAIRMAN. The next witness.

Mr. KLEINFELD. Mr. George Kremer. Is he here?

A VOICE. I expect him any moment.

Mr. KLEINFELD. Is there a representative here of Maas and Wald stein?

(No response.)

Mr. KLEINFELD. Mr. Masters.

The CHAIRMAN. Your name and address?

Dr. MASTERS. Edward J. Masters, 633 Fifth Avenue, New York City.

(The oath was administered by the chairman.)

TESTIMONY OF EDWARD J. MASTERS, PH. D., FACTORY MANAGER, HELENA RUBINSTEIN, NEW YORK, N. Y.

Mr. KLEINFELD. Dr. Masters, if I called you "mister" I apologize. Are you a medical doctor, sir?

Dr. MASTERS. No, sir.

Mr. KLEINFELD. What is your academic background?

Dr. MASTERS. Bachelor of science degree and masters degree in chemical engineering and Ph. D. in organic chemistry.

Mr. KLEINFELD. Not in pharmacology?

Dr. MASTERS. No.

Mr. KLEINFELD. What is your position with Helena Rubinstein?

Dr. MASTERS. Factory manager.

Mr. KLEINFELD. What do your duties entail?

Dr. MASTERS. They entail complete control of the factory operation, including purchasing, the laboratories, and production.

Mr. KLEINFELD. Please read your statement.

Dr. MASTERS. Pursuant to your request, we are herewith furnishing statement to be presented to your committee.

We are herewith listing Helena Rubinstein, Inc., products by generic designation as follows:

(The list of products referred to is in the files of the committee.)

Further to your request, we are herewith listing ingredients contained in our products, as follows:

(The list referred to is in the files of the committee.)

Colors; only certified colors and cosmetic nonaniline colors are used. The certified colors are allowable for use in food, drug, and cosmetic products, depending on their category. These are designated by F. D. & C and D. and C. numbers. The inorganic colors (nonaniline) used are the iron oxides, carbon blacks, ultramarine blue, violet, and chrome oxide greens. These latter are designated as cosmetic colors, and the guarantee that the amount of lead and arsenic present is as follows:

Less than 20 parts per million of lead and less than 1 part in 500,000 of arsenic are present.

(The list of the colors used is in the files of the committee.)

A laboratory, staffed by eight chemists, is maintained in our manufacturing plant. The chief chemist supervises laboratory operations and manufacturing operations, and is assisted by seven laboratory chemists. All our chemists possess qualifying academic degrees in science and/or chemistry; one chemist possesses a degree in pharmacy and is a licensed pharmacist in the State of New York.

Helena Rubinstein products are first compounded and studied on an experimental basis, using ingredients known for their long and continued use in cosmetics, having acceptance for use in cosmetics, and most of which appear as ingredients listed in the United States Pharmacopoeia, and/or other recognized and established compendia. The history and background of chemical ingredients are carefully studied and, after the determination of their safety for use is made, manufacture of a product, using these ingredients, may then proceed. A

large number of ingredients used in our manufacture are purchased from concerns, who have in turn carefully studied their particular product, so that these concerns are in a position to supply us with a warranty as to the safety of the ingredient alone, and in many cases the safety of the ingredient when used in combination with other ingredients. The details of the data compiled by manufacturers showing the warranty to us are always made available, in addition to the warranty delivered to us by the manufacturer. Our established policy is to purchase the best quality of raw materials and to make certain that deliveries are made strictly according to specifications agreed on. In all cases our laboratory does not approve a product for manufacture until a determination is made that the product is safe for use.

In any case where there is doubt concerning the ultimate decision as to the use of any ingredient or product, such ingredient or product is submitted to our consultant dermatologist for opinion and recommendation. In addition, such ingredient or product has also been submitted to an independent laboratory for analysis and report; in any event, we encourage and seek to obtain an objective study and report. At any time when a product calls for the use of an ingredient on which we do not have adequate experience, or conclusive history or literature, we consult with our medical adviser in order to obtain his opinion and recommendation. In some of these cases further laboratory testing or clinical testing may be recommended, or other recommendations may be made for the purpose of evolving a product which is considered safe and effective.

Some of the determinations we have on hand, before a product is released for sale, are as follows:

1. Laboratory tests have proved the product safe and effective for the purpose and use intended.
2. Sufficient use tests have been made to determine safety in use; some use tests are made on animals, and all have been made on humans.
3. Clinical tests in appropriate cases.
4. Shelf test over a long period of time to prove stability under normal conditions.
5. Special tests to prove stability under varying temperature conditions.

Manufacture of products is supervised by our chemists. At manufacture, a sample of each batch is taken by the laboratory, carefully examined, and approved for delivery to our production department for filling and finishing. During filling and finishing, a sample of the batch is taken by a chemist, carefuly examined, and approved for completion of filling. The sample taken by the chemist during the course of final filling and finishing is adequately marked and identified, and retained in our laboratory files.

With respect to our views on existing legislation covering the manufacture and sale of cosmetics, we firmly believe that it is the primary obligation and responsibility of the manufacturer to the public that any cosmetic manufactured and sold is safe for use. Our record of experience of injuries, or adverse reactions claimed to be due to the use of our products, clearly shows that complaints are in practically all cases due to personal allergies or personal sensitivities. Our record of complaints, in relation to the number of units of products sold and the infinitive number of individual number of applications repre-

sented, shows a negligible number of complaints. We consider our testing and the investigation of ingredients and products to be a serious responsibility, which we have always assumed, and will continue to assume as one of the major responsibilities of our company. In our opinion, additional legislation of practical intent will not add to our extensive testing and determination of product safety and efficacy.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Masters, does your company submit its products for acceptance to the committee on cosmetic of the American Medical Association?

Dr. MASTERS. It does not.

Mr. KLEINFELD. On page 6 of your statement you say:

> The details of the data compiled by manufacturers showing the warranty to us are always made available, in addition to the warranty delivered to us by the manufacturer.

What kind of warranty are you talking about?

Dr. MASTERS. Warranties that apply to raw materials purchased and also to raw materials that are suggested for use to us by the manufacturers.

Mr. KLEINFELD. What is warranted?

Dr. MASTERS. Let us take a specific example. In our estrogenic hormone cream we use natural estrogenic substance. We purchase this material strictly according to specifications. Before receipt of a shipment of the materials we insist that a biological assay is made on each shipment to guarantee to us that the material is as represented and meets all our specifications; and this is done on every shipment of a substance made in our laboratories.

Now, on further warranties, let us take, for example, the compound G4 and G11 which have come into use in the last few years in deodorant soaps and as fungicides. The specific manufacturer of those products has done considerable testing. The literature that he has compiled is given to us.

Mr. KLEINFELD. What kind of testing?

Dr. MASTERS. Toxicity test, actual-use tests, all sorts of clinical tests.

I have here, for instance, the type of literature that is submitted by a manufacturer on such products.

Mr. KLEINFELD. Does the warranty warrant that your suppliers has made various pharmacological and toxicologic tests?

Dr. MASTERS. Yes. For example, an example of what I mean——

Mr. KLEINFELD. What does the warranty say?

Dr. MASTERS. Let me give you a specific example here. Well, I have it here. Take one of the ingredients—Deltyl. The warranty will tell us they have done patch tests on 200 people and that the patch test has indicated that the response was negative in all cases.

Mr. KLEINFELD. You say you have a warranty. Do you have a written piece of paper which says, "We warrant something"?

Dr. MASTERS. Yes.

Mr. KLEINFELD. Do you have one with you?

Dr. MASTERS. Yes.

Mr. KLEINFELD. Please read it.

Dr. MASTERS. Well, I think there possibly is a misunderstanding. The warranty doesn't protect us from any possible damage. But here

is the type of warranty that is involved. Here is a letter written from an industrial toxicology laboratory to our supplier indicating: "Wish to submit the following report on a patch test."

Mr. KLEINFELD. Is that a letter to you from one of your suppliers?

Dr. MASTERS. This is a copy of a letter he gives us.

Mr. KLEINFELD. Who was the supplier?

Dr. MASTERS. Givaudan.

Mr. KLEINFELD. Is that a letter to you?

The CHAIRMAN. That is the copy of a letter received by your supplier from some toxicology laboratory; is that right?

Dr. MASTERS. That is right. I have a letter to us but I don't have it with me.

But, for instance, on the wetting agents we have received letters.

Mr. KLEINFELD. Do you have a letter addressed to you by any of your suppliers which warrants something?

Dr. MASTERS. Yes.

Mr. KLEINFELD. All right, please read such a letter.

Dr. MASTERS (reading):

We refer to your Order No. 2277——

Mr. KLEINFELD. To whom is that addressed?

Dr. MASTERS. To the H. R. Laboratories, Inc., which is Helena Rubinstein.

Mr. KLEINFELD. That is your company?

Dr. MASTERS. That is right; Helena Rubinstein.

Mr. KLEINFELD. By whom is it signed?

Dr. MASTERS. L. Osterweil, vice president.

Mr. KLEINFELD. What do they make?

Dr. MASTERS. They make the natural estrogenic substance.

We refer to your order No. 2277, your code No. 4–532, covering 250 grams of natural estrogenic substance, and, we have pleasure to send you herewith Seil, Putt & Rusby, Inc., certificate of analysis No. 65056 showing a melting point of 252.5/255.80C. and 95.5 percent Keto-Steroids.

We hope you will be satisfied with this fine analysis and assuring you that we are always glad to be of service to you, we remain——

and then the P. S.—

We also have pleasure in enclosing herewith Leberco Laboratory's biological assay showing 10,300,000 international estrone units per gram.

Mr. KLEINFELD. Is that the kind of warranty you are talking about?

Dr. MASTERS. Yes.

Mr. KLEINFELD. That is not the kind of warranty you told us about. That is the viewpoint of the chemist that this has certain potency in international units. It is a chemical warranty; is it not?

Dr. MASTERS. That is right.

Mr. KLEINFELD. It doesn't tell you how many tests were made or who made the tests at all.

Dr. MASTERS. Well——

Mr. KLEINFELD. It doesn't mention safety at all.

Dr. MASTERS. It doesn't mention safety.

Mr. KLEINFELD. Well then, your statement made earlier is not correct.

Dr. MASTERS. I have a letter from manufacturers of Foamole G and Detergent 1011 in which they specifically state that these ingredients have been tested and are safe for use.

Mr. KLEINFELD. It is the practice of your organization in obtaining a warranty to obtain such a letter from your suppliers in all instances?

Dr. MASTERS. Not in all instances.

Mr. KLEINFELD. In how many instances do you get a letter such as you just read, which doesn't mention in any particular what tests, if any, were made on materials, and in how many instances do you get some certification from your supplier that he or they have made safety tests as distinguished from chemical tests?

Dr. MASTERS. Practically all of the ingredients that we use in our manufacture are checked with the supplier prior to considering the ingredient for use, and in most cases they indicate to us that the raw material is safe for use. They also give us—we insist on obtaining literature which shows us the tests that have been run.

Mr. KLEINFELD. Do you buy wetting agents?

Dr. MASTERS. Yes; we do.

Mr. KLEINFELD. Do you obtain from the people who supply the wetting agents to you a warranty that the product will not cause any injury to the eyes?

Dr. MASTERS. No; we do not.

Mr. KLEINFELD. Do you put out a shampoo?

Dr. MASTERS. Yes; we do.

Mr. KLEINFELD. What kind of tests did you perform on your shampoo before you placed it on the market?

Dr. MASTERS. The tests specifically were use tests. The two shampoos that we placed on the market approximately 2 years ago were products that I personally had contact with for years, and they had been on the market previously with no adverse reaction. Recently we have run specific eye tests on these shampoos.

Mr. KLEINFELD. That was after the injuries which occurred?

Dr. MASTERS. That is right.

Mr. KLEINFELD. From the use of other shampoos not made by your company?

Dr. MASTERS. That is right.

Mr. KLEINFELD. Prior to that time you did not make tests to see whether the shampoos might cause injury to the eyes of the person using it?

Dr. MASTERS. No.

Mr. KLEINFELD. Do you use any animals now in determining whether such injuries might result?

Dr. MASTERS. In a specific test run, animals were used.

Mr. KLEINFELD. And you think those tests are necessary?

Dr. MASTERS. In my opinion the tests were not necessary, but in view of the possibility we believe it would be wise to test these two products.

Mr. KLEINFELD. You say you don't think it is necessary. Do you mean because you don't think a reasonable person would contemplate that shampoo might get into the eyes of an individual using it?

Dr. MASTERS. These two products had been on the market for years. There was no reason to suspect them. They were not new chemicals and they were not new cosmetics.

Mr. KLEINFELD. They were new when they were first put out; were they not?

Dr. MASTERS. For our company they were; yes.

Mr. KLEINFELD. At that time you did not conduct those tests, did you?

Dr. MASTERS. That is right.

Mr. KLEINFELD. Who performs your patch tests?

Dr. MASTERS. Ordinarily we do not perform patch tests.

Mr. KLEINFELD. On any of your products?

Dr. MASTERS. No. We perform irritation tests on animals, and we have done so in many cases in the last few years.

Mr. KLEINFELD. No patch tests?

Dr. MASTERS. No patch tests.

Mr. KLEINFELD. Do you perform use tests?

Dr. MASTERS. Yes, we do perform use tests.

Mr. KLEINFELD. Who performs the use tests?

Dr. MASTERS. Well, the laboratory performs these tests, distributes products to people in the factory; also within our organization in New York tests are run. We have what amounts to a panel for testing. We have a salon which tests hair preparations prior to use. And depending on the type of product, we may run these tests under the guidance of our dermatologist.

Mr. KLEINFELD. Do you have your own laboratory?

Dr. MASTERS. Yes, we do.

Mr. KLEINFELD. How many people are employed in your laboratory?

Dr. MASTERS. There are seven chemists that are employed, plus two other people that are not technical—nine.

Mr. KLEINFELD. You have seven chemists, two nontechnical people?

Dr. MASTERS. Yes.

Mr. KLEINFELD. No pharmacologist?

Dr. MASTERS. Yes, I have stated we have a chemist who is a pharmacist.

Mr. KLEINFELD. I said pharmacologist.

Dr. MASTERS. I am sorry. No pharmacologist.

Mr. KLEINFELD. You have no pharmacologist.

Dr. MASTERS. We have a consultant dermatologist on our staff who works on new products with us.

Mr. KLEINFELD. And you say—

In any case where there is doubt concerning the ultimate decision as to the use of any ingredient or product, such ingredient or product is submitted to our consultant dermatologist for opinion and recommendation.

Dr. MASTERS. That is right.

Mr. KLEINFELD. Who resolves the doubt? Who determines there is a doubt?

Dr. MASTERS. Well, the entire decision is made in collaboration. It definitely is the responsibility of the laboratory to decide whether a product is safe or not, but we certainly depend on the dermatologist for advice where we feel we are in a field that is foreign to us.

Mr. KLEINFELD. You feel then your chemists as chemists are qualified to perform all your tests and to determine whether your products are entirely safe?

Dr. MASTERS. Yes. Yes, we do feel that.

Mr. KLEINFELD. Is that customary in the cosmetic industry to rely on chemists?

Dr. MASTERS. Well, let me illustrate our procedure. Perhaps I haven't brought it out too clearly.

Before we put out a new product in which there is any doubt at all about the possibility of damage, we do run irritation tests involving skin tests and involving the eyes.

Mr. KLEINFELD. Pardon me. What are irritation tests? They are not patch tests?

Dr. MASTERS. No.

Mr. KLEINFELD. What are they?

Dr. MASTERS. For instance, on our deodorant cream, when we came out with that in 1949, we sent about seven formulas to a bacteriologist to test. This was done in the College of Physicians and Surgeons in the city here. And the tests involved shaving the hair of rabbits, shaving two areas, one to be used as a control and the other to be used for the actual product, scarifying both sides, and an application of the product on one of the sides. Then observation is made for any resultant irritation.

Also a certain amount of product is instilled into the eye for observation as to possible eye injury.

Included in the new products that we produced within the last 2 years we have our deodorant cream, our face powders, our suntan lotions, night cream, cleansing cream. All of these were submitted to this type of test. Now these tests indicated to us whether we have a primary irritant in our product. In those cases we obtained negative results. Now if we obtained positive results and were doubtful about it, we would get in the dermatologist and consult with him as to the interpretation of this test.

Mr. KLEINFELD. Before you go to your consulting dermatologist on how many people do you perform these irritation tests?

Dr. MASTERS. If we have any reason to believe that the product could be dangerous, we consult with our dermatologist at the very start of the testing prior to testing it on people.

Mr. KLEINFELD. So that before making any tests your chemists decide whether or not there may be some problem; is that right?

Dr. MASTERS. That is right.

Mr. KLEINFELD. And if you think there is no problem you don't make any tests?

Dr. MASTERS. No. As a matter of routine we run tests even if we feel the products are relatively innocuous.

Mr. KLEINFELD. What tests do you make when you think the products are relatively innocuous?

Dr. MASTERS. In most cases we submit the products to an outside laboratory for testing as a matter of routine.

Mr. KLEINFELD. What kind of testing?

Dr. MASTERS. This animal testing for irritation.

Mr. KLEINFELD. How many animals, do you know?

Dr. MASTERS. In some cases they may use nine animals for a sample, in other cases, two animals. For instance, in a case of deodorant cream we sent out seven samples. They used two animals for each sample. We varied the percentages of ingredients in the deodorant cream, the perfume, the active ingredients, to determine which direction we should go in our final formulation of the product.

Mr. KLEINFELD. You have a very flexible procedure, don't you?

Dr. MASTERS. That is right.

Mr. KLEINFELD. Do you think the testing you do would be accepted by the Committee on Cosmetics of the American Medical Association?

Dr. MASTERS. I am not sure that it would because our testing is a flexible one depending on good judgment and the nature of the product involved.

Mr. KLEINFELD. Depending on the judgment of your chemists, is that right?

Dr. MASTERS. Our chemists and dermatologist.

Mr. KLEINFELD. Well, you just said that if your chemists decided in advance there probably wasn't any problem, you wouldn't send it to the dermatologist.

Dr. MASTERS. Well, that could happen, yes.

Mr. KLEINFELD. Could happen?

Dr. MASTERS. Yes.

Mr. KLEINFELD. And you perform no patch tests?

Dr. MASTERS. No, ordinarily we don't perform any patch tests.

Mr. KLEINFELD. Do you put out any nail coat?

Dr. MASTERS. No, we do not put out any nail coat.

Mr. KLEINFELD. Have you ever put out any nail coat?

Dr. MASTERS. No.

Mr. KLEINFELD. How about nail polish?

Dr. MASTERS. Yes, we have a nail polish.

Mr. KLEINFELD. Have you ever received any complaint about it?

Dr. MASTERS. I don't recall any complaints that we have ever received in connection with our nail polish.

Mr. KLEINFELD. Do you manufacture all the products which you listed in your statement to this committee, or do you buy some of them from other concerns and put your label on them?

Dr. MASTERS. We do buy some products from other concerns and put our labels on them.

Mr. KLEINFELD. Products which are all made up?

Dr. MASTERS. That is right.

Mr. KLEINFELD. Do you test those products?

Dr. MASTERS. Well, certainly use tests are made on those products.

Mr. KLEINFELD. Who performs the use tests?

Dr. MASTERS. We perform the use tests ourselves before we consider putting it on the market.

Mr. KLEINFELD. On how many people?

Dr. MASTERS. The number could range from 50 to 200 people.

Mr. KLEINFELD. And those are performed by your chemists on personnel within your organization?

Dr. MASTERS. That is right.

Mr. KLEINFELD. No patch tests?

Dr. MASTERS. What is that?

Mr. KLEINFELD. No patch tests?

Dr. MASTERS. No. But the nature of the products that we purchase from outside sources are such that we normally do not expect any unusual reaction. For instance, the type of product put out included in this category would be a cologne stick. In other words, it is a solidified alcoholic solution of a perfume. We would set up the formula ourselves and ask the manufacturer to produce this for us, because there is a fire hazard in that specific case as far as manufacturing is involved. But as far as safety is involved, we would not expect such a product to be irritating. Yet all our use tests, actual use tests, the salon testing always acts as a check in these cases.

You may be interested in our actual statistics on complaints. I have had compiled for me our records, and last year we received 118 complaints of various nature. Most of them had to do with allergies. Now actually we produced about 20 million units; 118 complaints in 20 million units is really a very low figure. I don't see what we practically could do to better such a performance.

Mr. KLEINFELD. You might conduct adequate tests.

Dr. MASTERS. We do test our products.

Mr. KLEINFELD. Do you call adequate testing the kind of testing you referred to here where you don't even make a patch test?

Dr. MASTERS. Well, I am not a dermatologist, but the interpretation of a patch test is quite difficult for many products.

Mr. KLEINFELD. That is very interesting. And, therefore, should not somebody who is qualified to interpret the results make the tests?

Dr. MASTERS. If a patch test is made, I would say that certainly is true. But certainly use tests and basic toxicity tests and irritation tests supersede patch tests. Because when you are talking about 200 patch tests I don't think that guarantees safety at all.

Mr. KLEINFELD. We have had testimony from dermatologists that patch tests are important—and your tests are too.

Dr. MASTERS. I agree.

Mr. KLEINFELD. They have all said, and it is practically unanimous so far, that such tests should be conducted and evaluated by qualified physicians.

Dr. MASTERS. We have no objection to performance of patch tests, but our own testing procedure has proven to us to be quite sound as an actuality.

Mr. KLEINFELD. And again it is you chemists who perform your use tests; is that correct.

Dr. MASTERS. That is correct.

Mr. KLEINFELD. Just you chemists?

Dr. MASTERS. That is right.

Mr. KLEINFELD. Do you make your own lipstick?

Dr. MASTERS. Yes; we do.

Mr. KLEINFELD. You don't buy it from anybody?

Dr. MASTERS. No; we don't.

Mr. KLEINFELD. You market an estrogenic hormone cream and an estrogenic hormone oil, don't you?

Dr. MASTERS. Yes.

Mr. KLEINFELD. That is the "Hormone Twins" you advertise?

Dr. MASTERS. That is right.

Mr. KLEINFELD. When is the hormone cream used?

Dr. MASTERS. When is that used?

Mr. KLEINFELD. Yes.

Dr. MASTERS. I don't understand.

Mr. KLEINFELD. What is it recommended for and at what times is it supposed to be applied to the body?

Dr. MASTERS. I see. It is supposed to be used once a day. A 2-ounce supply of cream is a 30-day supply.

Mr. KLEINFELD. Is it supposed to be applied before a woman goes to bed?

Dr. MASTERS. We don't specify at what time she is to use it.

Mr. KLEINFELD. Do you specify to what areas of the body it is to be applied?

Dr. MASTERS. Yes, the face.

Mr. KLEINFELD. Just the face?

Dr. MASTERS. The face.

Mr. KLEINFELD. Not the neck or throat or any other portions of the body?

Dr. MASTERS. I am not sure of the throat. We may specify the throat, but I am not sure of that.

Mr. KLEINFELD. And what recommendations are made for your estrogenic hormone oil?

Dr. MASTERS. The same type of recommendation.

Mr. KLEINFELD. What is the difference between the two products? Why do you have two instead of one?

Dr. MASTERS. I am not sure of this, but I believe the estrogenic hormone oil is specified for the throat.

Mr. KLEINFELD. During the daytime?

Dr. MASTERS. I don't know.

Mr. KLEINFELD. Do you know what areas of the body are those to which the hormone oil is to be applied?

Dr. MASTERS. I believe it is only to the face, to the face and possibly the throat.

Mr. KLEINFELD. Did you perform any tests on your hormone products before you put them on the market?

Dr. MASTERS. Tests were performed under the guidance of our consulting dermatologist. They were run at the University of Vermont under Dr. Traub, and there were three main points that were determined at that time. One was whether we had efficacy; two, whether there was a safe dose; and three, whether the product formula itself was stable. I believe that the results indicate that the product was safe for use.

Mr. KLEINFELD. Do you have any reports to that effect?

Dr. MASTERS. The reports have never been published, but I must refer you to our dermatologist for the information, because all these tests were run strictly under his supervision.

Mr. KLEINFELD. What is the doctor's name?

Dr. MASTERS. Herman Sharlit.

Mr. KLEINFELD. And he is a dermatologist rather than an endocrinologist; is that correct?

Dr. MASTERS. That is right.

Mr. KLEINFELD. What statement do you put on the label of your hormone preparation?

Dr. MASTERS. We indicate how it is to be used. We indicate the amount, and we indicate the concentration of the active ingredients—10,000 international units per ounce.

Mr. KLEINFELD. Do you put any caution or warning label against using too much or rubbing the product in too long or applying it to other portions of the body for too long a period of time?

Dr. MASTERS. No.

Mr. KLEINFELD. You don't use the word "caution" or the word "warning" in your label?

Dr. MASTERS. No.

Mr. KLEINFELD. You concluded your statement, Dr. Masters, by saying:

In our opinion, additional legislation of practical intent will not add to our extensive testing and determination of product safety and efficacy.

I don't quite understand that. Please explain it.

Dr. MASTERS. As far as we are concerned, would our actual record be improved? That is our safety record. I have indicated it amounted last year to approximately 118 complaints in a usage of about 20 million units. Now you would have to strain to improve that record.

We don't object to legislation that is practical, but we feel that the tests we have performed on a practical basis have protected the public.

Mr. KLEINFELD. Do you make changes in the formulas of your products from time to time?

Dr. MASTERS. Yes, we do.

Mr. KLEINFELD. What do you do when you change the formula, as far as testing is concerned?

Dr. MASTERS. Well, the deodorant cream was a very excellent example of that. For instance, we had been using aluminum sulfate in our deodorant cream, and aluminum chlorhydrol had been brought to our attention, and we had been thinking of using aluminum chlorhydrol for quite some time. We decided to run a series of tests to determine whether we would have a better product, and we did so.

Mr. KLEINFELD. What kind of tests?

Dr. MASTERS. Well, first of all, one test that we ran were laundry tests. We made up various formulations, including aluminum sulfate and aluminum chlorhydrol, and we found that the formulation with aluminum chlorhydrol gave us a better result insofar as possible damage to clothing was involved.

Then we ran irritation tests. I previously referred to the submission of at least seven different formulas bearing the ingredients for animal testing, and we ran those tests as a precaution.

Then our actual use tests. The various samples of deodorants were distributed through our organization, and it may take 6 months to a year on such a product before we consider placing it on the market. In that time we did achieve a very good experience in regard to possible irritation.

Mr. KLEINFELD. It is not the established policy of your company then in connection with all of your new products or all combinations of substances which you put out to follow certain prescribed tests; is that correct?

Dr. MASTERS. It is not. For example, if we go into make-up items, style and fashion trends change, and the sales department may ask for a new shade or color. In such a case I don't think we would run irritation tests. We would formulate a product based on the same base and adjust the colors to produce the shade required. The possibility in that specific case, of bad reactions, is infinitesimal.

Mr. KLEINFELD. Do you make any soap?

Dr. MASTERS. Yes, we do.

Mr. KLEINFELD. Do you make the same tests, if any, with the soaps as are made with respect to your other cosmetic line?

Dr. MASTERS. Yes.

Mr. KLEINFELD. Do you know of any reason why the tests should not be made on soaps?

Dr. MASTERS. No.

Mr. KLEINFELD. The same problem exists, doesn't it?

Dr. MASTERS. Well, specifically, we had a little different problem, because our organization decided to place a deodorant soap on the

market. This involved the use of G–11. However, the base we were considering was a transparent soap base which was an entirely new formulation insofar as a deordorant soap was involved.

Now we had a wonderful literature indicating that there was no toxicity at all and no recognized allergic reaction to G–11, the active ingredient. However, we did submit this transparent deodorant soap to a bacteriologist and followed the standard testing procedures that had been adopted for that type of soap.

Mr. KLEINFELD. My question is this: If tomorrow you were to put out a soap containing some new ingredient or containing an untried combination of existing ingredients, would you want to use first the same careful tests you have used with your other cosmetics before putting the soap on the market?

Dr. MASTERS. Yes.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. You said the tests you make are designed to protect the public. Have you ever discarded a product as a result of such tests?

Dr. MASTERS. Yes, we have.

The CHAIRMAN. Now the law does not require you to make any tests; is that not right?

Dr. MASTERS. That is right.

The CHAIRMAN. At the present time?

Dr. MASTERS. Yes.

The CHAIRMAN. Do you think a man who makes no tests should go on unmolested?

Dr. MASTERS. No, I do not feel that. I feel that tests should be made.

The CHAIRMAN. Mr. Jones?

Mr. JONES. No questions.

The CHAIRMAN. Mr. Horan?

Mr. HORAN. No questions.

The CHAIRMAN. Mr. McDONOUGH?

Mr. McDONOUGH. How long has your firm been in business in this cosmetic production?

Dr. MASTERS. Approximately 30 years.

Mr. McDONOUGH. And how many years back have you been using these various organic chemicals you outline here as part of your ingredients?

Dr. MASTERS. Well, it depends on the specific chemical.

Mr. McDONOUGH. I understand that.

Dr. MASTERS. The usage goes back in many to the start of the business. In some cases the ingredients are newer in nature and their history in our organization is perhaps about 4 or 5 years. It all depends on the specific chemical.

Mr. McDONOUGH. How long have you been with the firm?

Dr. MASTERS. I have been with the firm 4 years.

Mr. McDONOUGH. Previous to that, were you in the manufacture of cosmetics?

Dr. MASTERS. Yes, I was. I had the same type of position as I hold at present.

Mr. McDONOUGH. Do you think that the claims for cosmetics in their advertising are equal to the performance of the product?

Dr. MASTERS. That's a very difficult question to answer because it involves opinion. But perhaps—let me tell you what we do about it. We have a product that we feel is ready for marketing and we write up what this product is supposed to do. We submit that to our legal department and also to our copy department. They, in turn, write up label copies and advertising copy, submit it to our legal department as a check, and also return it to us for approval. We may either approve it or disapprove it.

Mr. MCDONOUGH. In other words, you check and double check on your copy before you submit it to the public?

Dr. MASTERS. That is right. In other words, we have a legal check on our copy and also have a technical check. In other words, I don't believe that there is a product in our line that we produce where we cannot substantiate a claim.

Mr. MCDONOUGH. Out of the 118 complaints that you had due to problems involving allergies and otherwise, have you had any complaints about your advertising for claiming more than the product will produce?

Dr. MASTERS. No, I don't recall receiving any such complaints.

Mr. MCDONOUGH. That is all, Mr. Chairman.

The CHAIRMAN. That is all, thank you.

Mr. KLEINFELD. Mr. Kremer.

The CHAIRMAN. Your name and address?

Mr. KREMER. George Kremer, Jr., 1841 Park Avenue, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF GEORGE KREMER, JR., PRESIDENT, ROUX LABORATORIES, INC., NEW YORK CITY

Mr. KLEINFELD. You are president of the Roux Laboratories?

Mr. KREMER. I am.

Mr. KLEINFELD. Please read your statement.

Mr. KREMER. We are pleased to give the committee information regarding Roux products.

Roux products are made in a modern factory which has the finest equipment available. Stainless steel and glass-lined tanks, modern mixing and similar equipment, plus automatic filling and packaging equipment, is used to facilitate the production of the finest finished products.

These products are manufactured from chemicals which are of the highest quality obtainable. They are purchased from such reliable firms as E. I. du Pont de Nemours, Dow Chemical Co., Shell Oil Co., Procter & Gamble, Charles Pfizer, and others of like caliber. In addition to the guaranties of the manufacturers, raw materials are tested by chemists employed by Roux.

Each batch of every Roux product is manufactured under a system of elaborate controls. In addition to Roux's customary chemical testing, samples are tested on living models in Roux's testing center. It is only after all tests prove satisfactory that the batch is packaged and marketed.

Before a new product is marketed, a thorough search of the available literature is made and such literature is carefully studied. A state-

ment is obtained from the manufacturers as to their experience with any new chemicals. Once the ingredients have been decided upon and the product developed, it is tested in Roux's laboratory completely and thoroughly. It is then submitted to a recognized independent laboratory for testing, including patch testing on humans. Following this, the product is used in the Roux testing center on living models for a long time. The product is also usually provided to select beauty salons where it undergoes additional testing. It is only then, after the product has satisfactorily passed each of these tests, that it is finally sold on the open market.

The bulk of our business is the manufacture of hair colorings which require a patch test before every application by each user. Therefore, if any harm could come to a user, timely, certain and adequate warning is given to the user and complete safety is provided. This element of protection of the public was incorporated in the law after long and careful consideration by the Congress.

Roux is extremely careful to have its labeling and directions in simple language which is easily understood by the public. The directions are adequate, detailed, and comprehensive.

During the 19 years that Roux has been in business, it has carried products liability insurance with the same company and its rates have been reduced by 75 percent because of favorable experience in spite of the fact that the amount of coverage has been increased a hundredfold. Thus, our $1,000,000 of insurance coverage now costs us but 25 percent as much as $10,000 of coverage formerly cost us.

It is our opinion that present laws are adequate if reasonably and properly enforced by competent administration.

Mr. KLEINFELD. In paragraph 2 of your statement, you say you obtain guaranties from your manufacturers.

What is guaranteed?

Mr. KREMER. I think the meaning of that would be the specifications. In other words, it was bought as a U. S. P. product or an N. F. or a chemical pure product.

Mr. KLEINFELD. That guaranty has nothing to do with the safety tests; is that not correct?

Mr. KREMER. No, sir; it has nothing to do with it.

Mr. KLEINFELD. Pardon me?

Mr. KREMER. No; it has nothing to do with it.

Mr. KLEINFELD. You say each batch of your product is manufactured under a system of elaborate controls, and you discuss your customary chemical testing. Those tests also are designed to ascertain whether the product is up to specifications?

Mr. KREMER. That is right.

Mr. KLEINFELD. Then you say:

Before a new product is marketed, a thorough search of the available literature is made and such literature is carefully studied.

Who makes such a search?

Mr. KREMER. One of the chemists in our organization.

Mr. KLEINFELD. How many chemists do you employ?

Mr. KREMER. Six.

Mr. KLEINFELD. Do you have anybody else to do such testing?

Mr. KREMER. We use consulting chemists and firms as well.

Mr. KLEINFELD. But for your routine testing with respect to safety, that is done by your chemists; is that correct?

Mr. KREMER. The reference in paragraph 3 is to the chemical testing of the materials as manufactured.

Mr. KLEINFELD. Exactly what tests does your company make to determine that your product will not cause injury before you put the product on the market?

Mr. KREMER. I think I can best answer that by giving an illustration of one.

Mr. KLEINFELD. Please speak louder. I do not think the committee can hear you.

Mr. KREMER. Sorry. I think I can best answer that by giving an illustration of one of our recent products, which happened to be a hair shampoo.

Mr. KLEINFELD. When did you put it out?

Mr. KREMER. Pardon?

Mr. KLEINFELD. When did you put it out?

Mr. KREMER. That was marketed in the spring of 1950. Work was begun on that product in February 1947. A search of literature was made by one of our people.

Mr. KLEINFELD. One of your chemists?

Mr. KREMER. Yes. Similiar products on the market were checked by these chemists. We retained at that time, February 1947, a very well-known soap chemist to do the experimental work on this particular product in conjunction with our own people. Laboratory work was done——

Mr. KLEINFELD. What kind of laboratory work, do you know?

Mr. KREMER. Testing of various products, raw materials, and so on.

Mr. KLEINFELD. I still don't know what you mean by "so on." What kind of tests were actually made? Do you know? On animals, humans?

Mr. KREMER. These were chemical tests.

Mr. KLEINFELD. To determine chemical composition?

Mr. KREMER. First they wanted to develop the product and then make the safety tests.

Mr. KLEINFELD. Now you are developing your product?

Mr. KREMER. That is right.

Mr. KLEINFELD. All right.

Mr. KREMER. Literature was searched. Similar products were tested. The laboratory work was done on it. The products were used in our testing center beginning in the early part of 1949. They were used for a period of over a year in our own testing center.

Mr. KLEINFELD. They were used in your testing center?

Mr. KREMER. Yes.

Mr. KLEINFELD. What is the testing center and who used it?

Mr. KREMER. We have three licensed beauticians that work in our own plant, and they do work on living models. We have these models that come in to us day after day, year after year, and they are use tests. In other words, the product must be suitable for the purpose for which it is intended. So I would say with this particular product they probably washed several thousand heads of hair.

The CHAIRMAN. You say probably washed. Have you anything definite?

Mr. KREMER. I would guarantee two or three thousand, sir.

The CHAIRMAN. Two or three thousand different people?

Mr. KREMER. No; probably four or five hundred different people have it used on them every 3, 4, 5, 6 weeks.

The CHAIRMAN. Where do these people come from?

Mr. KREMER. All over New York.

The CHAIRMAN. Why do they come to this testing place?

Mr. KREMER. Because we do free work.

Mr. MCDONOUGH. You mean they are volunteers and you give them the service in order to test your product?

Mr. KREMER. That is right.

Mr. MCDONOUGH. Do you assume any responsibility if you injure them?

Mr. KREMER. I assume we would be responsible, sir.

Mr. MCDONOUGH. That is part of your insurance policy, is it not?

Mr. KREMER. Yes, it would be.

Mr. MCDONOUGH. Who watched these tests as they were performed?

Mr. KREMER. They are watched by the chemist in charge of the research work and also by the beautician who is doing the work.

Mr. MCDONOUGH. No doctor or dermatologist?

Mr. KREMER. No doctor at this time. When the experimental work was concluded after 3 years. the final product was submitted to an independent research laboratory for patch testing.

Mr. MCDONOUGH. You still don't talk loud enough, Mr. Kremer.

Mr. KREMER. I am sorry. After the product development was concluded at the end of 3 years, the finished product was submitted to an independent testing labortary for patch testing on human beings. When these tests were concluded, the product was marketed.

Mr. KLEINFELD. This independent laboratory, what facilities does it have for doing this testing?

Mr. KREMER. It is a recognized testing laboratory where they have models come in right along.

Mr. KLEINFELD. Do they employ a dermatologist?

Mr. KREMER. Frankly, I couldn't say. I know there is a doctor.

Mr. KLEINFELD. Pardon me?

Mr. KREMER. I know there is a doctor.

Mr. KLEINFELD. A medical doctor?

Mr. KREMER. Yes.

Mr. KLEINFELD. What is his name?

Mr. KREMER. Dr. John Killian.

Mr. KLEINFELD. You say, "on this particular product." Was it a shampoo?

Mr. KREMER. Yes.

Mr. KLEINFELD. On which you did about 3 or 4 years' testing?

Mr. KREMER. We worked from its inception in February 1947, and the product finally sold April 1950.

Mr. KLEINFELD. Are you saying you do that sort of testing on all your products before putting them on the market?

Mr. KREMER. That is done on all new products. It might not take quite as long for some. It varies.

Mr. KLEINFELD. It might take years?

Mr. KREMER. Not necessarily. It might take a year, others might take more.

Mr. KLEINFELD. Do you put out a nail undercoat?

Mr. KREMER. No, sir; we do not.

Mr. KLEINFELD. Did you ever?

Mr. KREMER. No, sir.

Mr. KLEINFELD. You never put out a fingernail base coat by the name of Fixt?

Mr. KREMER. No, sir.

Mr. KLEINFELD. You never sold it or made it?

Mr. KREMER. I think there is confusion here. I am testifying for Roux Laboratories, Inc. They make no nail enamels at all.

Mr. KLEINFELD. What is your connection with Roux Distributing Co.?

Mr. KREMER. They are the purchaser of some of our products.

Mr. KLEINFELD. Sir?

Mr. KREMER. They buy cosmetic products from us.

Mr. KLEINFELD. Is Roux Distributing Co. a subsidiary of your company?

Mr. KREMER. No; it is not.

Mr. KLEINFELD. What is the connection, if any?

Mr. KREMER. Buyer and seller, and I happen to be an officer of both corporations.

Mr. KLEINFELD. Officer of both corporations?

Mr. KREMER. Yes, I am.

Mr. KLEINFELD. Do you have a copy of our telegram to you, sir?

Mr. KREMER. Yes, I do.

Mr. KLEINFELD. May I see it? Do you have them all there?

(Mr. Kremer hands telegrams to Mr. Kleinfeld.)

Mr. KLEINFELD. Our first telegram to you, sir, was addressed to the Roux Distributing Co. Is that not correct?

Mr. KREMER. That is right.

Mr. KLEINFELD. Therefore can you testify on behalf of Roux Distributing Co.?

Mr. KREMER. I can; yes.

Mr. KLEINFELD. Let's do so. What is the Roux Distributing Co.?

Mr. KREMER. A sales company.

Mr. KLEINFELD. What does it sell?

Mr. KREMER. Cosmetic products.

Mr. KLEINFELD. What kind of cosmetic products?

Mr. KREMER. Primarily colorings for hair. They also sell shampoo products, nail enamel, and so on.

Mr. KLEINFELD. Do they manufacture these products?

Mr. KREMER. No; they do not.

Mr. KLEINFELD. Where do they obtain them?

Mr. KREMER. The bulk of its requirements is obtained from Roux Laboratories, Inc.

Mr. KLEINFELD. And does the Roux Distributing Co. rely in all cases on the testing by Roux Laboratories, Inc.?

Mr. KREMER. On all the products which it buys from Roux Laboratories, Inc.

Mr. KLEINFELD. Where did the Roux Distributing Co. obtain the fingernail base coat called Fixt?

Mr. KREMER. That was purchased from the Durlin Corp.

Mr. KLEINFELD. I can't hear the name.

Mr. KREMER. Durlin.

Mr. KLEINFELD. Do you know what tests were performed on that product before it was put on the market?

Mr. KREMER. Yes, I do.

Mr. KLEINFELD. What tests were performed and by whom?

Mr. KREMER. Use tests were performed by our testing center for a period of about 3 months on the nails of many individuals before it was sold.

Mr. KLEINFELD. How many individuals?

Mr. KREMER. It is quite some time back. I would judge possibly a hundred.

Mr. KLEINFELD. For what period of time?

Mr. KREMER. I would say over a period of 3 months.

Mr. KLEINFELD. I thought you said that most of your products or all of your products were tested about a year, 2 years, 3 years, 4 years.

Mr. KREMER. That is the products we manufacture. This is a product which was purchased in finished form by Roux Distributing Co.

Mr. KLEINFELD. Did you ask the company from which you had purchased the product what tests it had made?

Mr. KREMER. We had the customary guarantee from the manufacturer.

Mr. KLEINFELD. What did the guarantee say?

Mr. KREMER. It is a standard hold-harmless guarantee and complies with the Food, Drugs, and Cosmetics Act.

Mr. KLEINFELD. That doesn't necessarily mean they performed adequate testing, does it?

Mr. KREMER. I suppose it doesn't.

Mr. KLEINFELD. You say you suppose it doesn't?

Mr. KREMER. I suppose it doesn't.

Mr. KLEINFELD. Did you ever recall from the market your fingernail base coat.

Mr. KREMER. Frankly, I don't recall.

Mr. KLEINFELD. Beg pardon?

Mr. KREMER. I do not recall. I know the material was destroyed on our premises by the manufacturer.

Mr. KLEINFELD. Do you know why?

Mr. KREMER. No; I don't.

The CHAIRMAN. If you distributed this, don't you know whether or not you recalled it?

Mr. KREMER. Frankly, I don't recall, sir. I do recall this: After a certain period of time—we are a very small vender of this type of products. I don't think our total purchases of this particular product amounted to $200 in the course of time we sold it. It was a finished product. I know this: We had no complaints on it at the time the manufacturer came to see us and said they wanted to take it off the market, and they came into our place and took the material and destroyed it and paid us for it.

The CHAIRMAN. You didn't do the same with your buyers, did you?

Mr. KREMER. No; I did not as far as I know.

The CHAIRMAN. All right.

Mr. KLEINFELD. Do you submit any of your products to the Committee on Cosmetics of the American Medical Association?

Mr. KREMER. No, sir; we do not.

Mr. KLEINFELD. Is the list of your products which you gave us in your second telegram of December 28, a complete list of all the products which you make?

Mr. KREMER. I believe it is.

Mr. KLEINFELD. Are the ingredients which you specify in that telegram a complete list of all the ingredients contained in all your products?

Mr. KREMER. These are the major ingredients which we use.

Mr. KLEINFELD. We asked you to submit a list of all your ingredients, didn't we, sir?

Mr. KREMER. I believe you did.

Mr. KLEINFELD. Is there any reason why you wouldn't give us a statement of all the ingredients?

Mr. KREMER. Except it so happened when this original wire was received I was not in New York. I was in Minnesota. Apparently you folks were in a hurry by wiring, so when I came back I gave as comprehensive a list as possible of the substantial materials which we use.

Mr. KLEINFELD. Since then have you had an opportunity to give us a complete list?

Mr. KREMER. It would probably run into hundreds of chemicals.

Mr. KLEINFELD. That is right.

Mr. KREMER. It probably would.

Mr. KLEINFELD. Do any of your products contain paraphenylenediamine?

Mr. KREMER. Yes, they do.

Mr. KLEINFELD. Did you mention that in your telegram to us?

Mr. KREMER. Yes.

Mr. KLEINFELD. Did you?

Mr. KREMER. Yes.

Mr. KLEINFELD. You may use some other term. What term do you employ?

Mr. KREMER. Aromatic amine.

Mr. KLEINFELD. Is that the same thing?

Mr. KREMER. Yes.

Mr. KLEINFELD. In what product do you employ that?

Mr. KREMER. In many of our hair dyes.

Mr. KLEINFELD. When you say aromatic amine, isn't that a general class of product, a generic term?

Mr. KREMER. An oxidation type of dyestuff, aniline dye.

Mr. KLEINFELD. How many dyes or colors are included in that term?

Mr. KREMER. It probably includes thousands.

Mr. KLEINFELD. How many do you use?

Mr. KREMER. Principally paraphenylenediamine.

Mr. KLEINFELD. In connection with your hair dyes, hair bleaches, hair lacquers, hair rinses, hair crayons, hair dressing, and hair shampoo, which are all employed, of course, on the hair, do you in your long testing determine whether or not any damage would be done to the eye by reason of the use of these products?

Mr. KREMER. Most of these products, particularly the hair dyes, which are the bulk of our business, all carry a caution notice to the effect that it should not be used in around the eyes; to do so may cause blindness. That is required by law—they should not be used around the eye.

Mr. KLEINFELD. How about your hair shampoo—does that contain such a warning?

Mr. KREMER. No, sir; it does not.

Mr. KLEINFELD. Pardon me?

Mr. KREMER. It does not.

Mr. KLEINFELD. Before you put out your hair shampoo and when you conducted these long and thorough tests you have discussed, did any of your employees try to ascertain whether or not it might cause any damage to the eye of a person?

Mr. KREMER. I did.

Mr. KLEINFELD. You didn't use animals, did you?

Mr. KREMER. I did myself.

Mr. KLEINFELD. What kind of tests?

Mr. KREMER. I did.

Mr. KLEINFELD. You used it yourself?

Mr. KREMER. That is right. I used it on myself and put it in the eye in the normal course of use. I used it repeatedly, regularly.

Mr. KLEINFELD. Are you a physician or technically qualified?

Mr. KREMER. No, sir.

Mr. KLEINFELD. You didn't have any physician or dermatologist check that?

Mr. KREMER. The use in the eye—no, sir.

Mr. KLEINFELD. Did you use it in the eye of any animal or other person besides yourself?

Mr. KREMER. No, sir.

Mr. KLEINFELD. You conclude your statement by saying it is your opinion that present laws are adequate if reasonably and properly enforced by competent administration. Please go into some detail on that. What do you mean by that?

Mr. KREMER. Well, the reason for that opinion is that based on our experience over a period of 19 years, I see no real need for further legislation. I think the legislation which now covers our particular segment of the industry, that is, section 601 of the Federal Food, Drug, and Cosmetic Act is adequate and provides complete protection for the user if carefully and properly used.

Mr. KLEINFELD. Are you familiar with the fact that in the last few months, within the last 6 months, I think, some shampoos were put on the market which, because they got into the eyes of some of the people using them, caused rather serious eye injury?

Mr. KREMER. I had heard about it.

Mr. KLEINFELD. How would reasonable and proper enforcement by competent administration have prevented those injuries?

Mr. KREMER. Well, they have the power of seizure.

Mr. KLEINFELD. Does that help the injury to the eye?

Mr. KREMER. No. The products can be taken off the market.

Mr. KLEINFELD. After the injury has resulted; is that correct?

Mr. KREMER. I don't know if that injury really resulted or not. I have no knowledge of it. It is purely hearsay as far as I am concerned.

Mr. KLEINFELD. Let's assume for the sake of argument that some shampoos were placed on the market, that ingredients were used and were not tested before being placed on the market. Let's assume for the sake of argument that all the manufacturer had to do was to take a few drops of the shampoo and put them in the eyes of a rabbit, in

which case he or some competent person could have determined that injury was being caused in consequence. Let's assume that the manufacturers of those products did not perform even that simple test and put the product on the market as a shampoo, and that the shampoo got in a number of persons' eyes and caused fairly serious eye damage. Now, assuming those facts to be correct, how would reasonable and proper enforcement by competent administration have prevented those injuries?

Mr. KREMER. Frankly, if you are asking my opinion, I am not qualified.

Mr. KLEINFELD. You did make the statement that present laws are adequate.

Mr. KREMER. As far as our firm is concerned, I think they are quite adequate.

Mr. KLEINFELD. Let's talk about other firms.

Mr. KREMER. Pardon?

Mr. KLEINFELD. Let's talk about other firms.

Mr. KREMER. I have no knowledge of other firms. You made mention of using this material in the eyes of rabbits. I don't know of a certainty that would have precluded these alleged injuries. Do you?

Mr. KLEINFELD. Yes; we have——

Mr. KREMER. I don't—pardon me.

Mr. KLEINFELD. We have been told by competent authority the injury would have promptly showed up in a rabbit's eye.

If that is correct, again I ask you, using the words you used in your statement, how would reasonable and proper enforcement by competent administration have prevented those injuries?

Mr. KREMER. I am going to go back to your rabbit tests. I know of my own experience that rabbit tests are extremely inconclusive.

Mr. KLEINFELD. Well, do you think the manufacturer, then, should put it in his own eyes?

Mr. KREMER. If it is good enough for the public, it is good enough for me, and why use them?

Mr. KLEINFELD. You put it in your own eyes?

Mr. KREMER. That is right.

Mr. KLEINFELD. Suppose you had seen damage to the eye. Would you have put it on the market?

Mr. KREMER. Certainly not.

Mr. KLEINFELD. Would you consider yourself negligent if you put it on the market without putting it in your eye?

Mr. KREMER. In that particular product, yes.

Mr. KLEINFELD. How would reasonable and proper enforcement by competent administration force you to put that product in your eye before you put it on the market?

Mr. KREMER. Well, I don't think they could have forced me to do it. The good name of the company would force me to do that, and reputation. Any manufacturer that is reputable——

Mr. KLEINFELD. The law wouldn't require you to do that, would it?

Mr. KREMER. No. You say about rabbit tests. If the law required rabbit tests, possibly there would be no product on the market at all.

Mr. KLEINFELD. Why is that?

Mr. KREMER. Because I think you can cause damage in the eye of a normal rabbit with plain water.

Mr. KLEINFELD. Well, you apparently differ from all the dermatologists that have testified before this committee. Do you think you are qualified to?

Mr. KREMER. I have my own experience on it, sir.

Mr. KLEINFELD. You do take some precautions, don't you?

Mr. KREMER. I surely do. But we are getting back to the rabbit. I differ distinctly from my own experience on rabbits.

Mr. KLEINFELD. Let's take some other animal you prefer—guinea pigs?

Mr. KREMER. No.

Mr. KLEINFELD. What animal would you use?

Mr. KREMER. If it is going to contact the eye of a human, I think it should in small doses be used in the eye of a human.

Mr. KLEINFELD. Used in the eye of a human?

Mr. KREMER. Oh, yes.

Mr. KLEINFELD. Before making any other preliminary tests?

Mr. KREMER. I don't say that. You must search your literature, must make all normal tests and precautions would be taken, then it can be used, and you can certainly determine if it is safe by using it in dilute quantities in the eyes of a human.

Mr. KLEINFELD. In discussing a product such as you put out which is used in and around the orbital area—the eyes, eye lashes, and hair—is it not a fact that careful tests of some sort must be made to see to it in advance that injuries to consumers' eyes won't result?

Mr. KREMER. Which product do you have reference to?

Mr. KLEINFELD. The products you make—shampoos, hair dyes.

Mr. KREMER. Hair dyes are not used around the eyes.

Mr. KLEINFELD. Shampoos.

Mr. KREMER. They might possibly make contact with the eyes.

Mr. KLEINFELD. Then you want to make tests on the eyes, don't you?

Mr. KREMER. I would say so; yes.

Mr. KLEINFELD. Before the product is put out?

Mr. KREMER. That is right.

Mr. KLEINFELD. Well, the present law doesn't require that any such tests be submitted to the Food and Drug Administration or anybody else. Is that not correct?

Mr. KREMER. That is correct.

Mr. KLEINFELD. Then how could more vigorous enforcement have prevented these difficulties?

Mr. KREMER. Well, I think that those products—I know very little about it, and this is purely an opinion of mine.

Mr. KLEINFELD. If you know very little about it, why do you say present laws are adequate?

Mr. KREMER. I am speaking solely for our firm. It is no concern of ours for anyone else in the industry. This is our business I am speaking about now.

Mr. MCDONOUGH. Will counsel yield there?

Mr. KLEINFELD. Yes, sir.

Mr. MCDONOUGH. Mr. Kremer, of course, the committee is interested in the protection of the public generally. And as much as you may feel confident that your product is not detrimental to the human system in any way and you use all precautions you know of to protect them

against it, we want your opinion as a manufacturer of cosmetics as to whether the law is adequate to protect the public in general against all cosmetic manufacturers. And now, in view of that, do you think your last statement is comprehensive enough?

We are not concerned particularly about your firm, except from the bad experience you had. But what do you think of the cosmetic industry as a whole, large and small, people that have laboratories, people that do not have laboratories, people that make the stuff in bathtubs and sell it in small distributing centers? You know what I mean—this business is a big and small business, is it not?

Mr. KREMER. Yes.

Mr. MCDONOUGH. There are all kinds of people in it. What is your opinion of that?

Mr. KREMER. Well, the conversation here has been about a law similar to the drug law, and I don't know too much about it. But I don't think the drug law has eliminated injuries from drugs. I don't think you can legislate against injuries. You can't legislate——

Mr. MCDONOUGH. You can't legislate against automobile accidents, either.

Mr. KREMER. That is right.

Mr. MCDONOUGH. You may give an automobile to a man and he drives 100 miles an hour and kills somebody. But there are precautions taken against that. Do you think there is enough precaution in the present Cosmetic Act to protect the public against deleterious effects?

Mr. KREMER. I think the record of the industry speaks for itself, and I think it is a very good record. The incidents I have picked up here are a few. Actually I don't know the date of Koremlu. There has been conversation about that since the time I went into this industry about 25 years ago. I remember something about Koremlu.

So in order to justify additional legislation they are going pretty far back, because that was either before the present law was enacted or at about that time.

So in that time, as an argument for additional legislation, we have some lacquer pads, which were caused by a scarcity of shellac during the last war; we have base coats, which apparently caused injury to certain individuals' fingernails; we have Koremlu, which goes way back; and then there is a shampoo now. So, over a period of 13 years, we have four products, with all these, as you say, bathtub manufacturers and reputable manufacturers, and there were four instances over many billions of applications of products, and that is used as an indictment of the industry as a whole.

The CHAIRMAN. The industry hasn't been indicted. As a matter of fact, some of you people have insisted this committee include cosmetics in this investigation. It was never intended in the first instance, but members of your industry and one of the men who testified here yesterday came to Washington and went to the various offices of the members of this committee and insisted that they include cosmetics in this investigation. There is no indictment here.

Mr. KREMER. Perhaps my choice of language was ill chosen. But there are four cases that are being used now against the industry as a whole. I personally feel that the industry has an excellent record.

The CHAIRMAN. Do you feel that this committee is using four cases against the industry?

Mr. KREMER. Again my——

The CHAIRMAN. We are using them against no one.

Mr. KREMER. Again my choice of language was unfortunate here. I didn't mean that.

Mr. MCDONOUGH. There is a statement here in paragraph 5 of your statement in which you say:

> The bulk of our business is the manufacture of hair colorings which require a patch test before every application by each user. Therefore, if any harm could come to the user, timely, certain and adequate warning is given to the user and complete safety is provided. This element of protection of the public was incorporated in the law after long and careful consideration by the Congress.

What law are you referring to?

Mr. KREMER. The Food, Drug, and Cosmetics Act.

Mr. MCDONOUGH. For patch testing?

Mr. KREMER. There was special consideration at that time given to hair colorings, a lot of scientific evidence submitted. There were arguments pro and con, and hair colorings of the type which we manufacture were considered especially and dealt with especially. They require a caution notice on the package, they require a caution notice on the bottle, and they require adequate instructions in the directions for this patch-testing before every application.

Mr. MCDONOUGH. That was authority that the Food and Drug Administration had. I don't recall any recent act of Congress that covers it.

Mr. KREMER. That was incorporated in the law, as I understand it.

Mr. MCDONOUGH. You mean that applies to hair coloring alone?

Mr. KREMER. That is right.

Mr. KLEINFELD. Then your product under the present law contains dyes which may cause blindness; is that right?

Mr. KREMER. No. That is what we are required to put on the label. I know of no such instance.

Mr. KLEINFELD. Why are you required to put it on the label?

Mr. KREMER. Required by law.

Mr. KLEINFELD. Do you know why the law requires that?

Mr. KREMER. Yes. There was a good deal of agitation a good many years ago caused by some of these products being used to dye eye lashes and eye brows. There were some injuries on it because the orbital area is more sensitive than the skin of the scalp and it is hard to patch-test around the eyes. And there were some injuries due to allergy in that area.

Mr. KLEINFELD. Blindness was caused by some of those products, was it not?

Mr. KREMER. I have no knowledge of that.

Mr. KLEINFELD. Well, it was reported in the hearings of Congress when this law was passed that a woman had been blinded by various dyes and various hair preparations.

Mr. KREMER. I will take your word for it. I have no knowledge.

Mr. KLEINFELD. Your product does contain a caution statement that its use may cause blindness?

Mr. KREMER. That is right.

Mr. KLEINFELD. Were you here when Dr. Pillsbury testified yesterday?

Mr. KREMER. I was here during part of it.

Mr. KLEINFELD. Did you hear him say he favors additional legislation because certain types of cosmetics have unquestionably produced moderate to severe damage to the human body in the past, and because a very large number of chemical compounds having potential uses in cosmetics have become available during the past 10 years, and because under present regulations it is entirely possible for a manufacturer to introduce a new cosmetic to the public with almost complete disregard of the safety of the compound?

Mr. KREMER. I believe I heard that.

Mr. KLEINFELD. You disagree with it, then; is that right?

Mr. KREMER. No; I am inclined to go along with his theory. However, new chemicals are in everything we eat, wear, touch. We also have those same new chemicals in those things.

I believe Dr. Pillsbury made some statement about paraphenylenediamine yesterday. On that basis you should have legislation for clothes, fur, feathers, rubber, leather, everything containing a similar material.

Mr. KLEINFELD. You don't think the fact that cosmetics are applied directly to the body is an important thing, more important than the wearing of fur?

Mr. KREMER. I think you will find incidence of injury is at least as great and perhaps greater in these things you are referring to, in clothes, rubber, feathers.

Mr. KLEINFELD. Are you qualified to make that statement? What business are you in besides cosmetics?

Mr. KREMER. That is the only business I am in.

Mr. KLEINFELD. Let's talk about cosmetics.

Mr. KREMER. I will refer you to——

Mr. KEINFELD. From what you say, do you mean we should not take any precautions, or try to do the best we can?

Mr. KREMER. I am in favor of doing the very best we can. I would like to explain my position. I don't care as far as we are concerned. We do the testing; we do everything possible to produce a safe and proper product for the public, to safeguard their health and to safeguard our reputation.

Mr. ABERNETHY. Mr. Chairman, I think the witness' position is clear. He said he didn't think we needed legislation. We may disagree with him. Let's move on to something else.

Mr. KLEINFELD. That is all I have

The CHAIRMAN. Any questions?

Mr. HORAN. No questions.

Mr. JONES. No questions.

The CHAIRMAN. That is all, sir.

We will adjourn until 2 o'clock.

(Whereupon, at 12:40 p. m., a recess was taken until 2 p. m. of the same day.)

AFTERNOON SESSION

The CHAIRMAN. The committee will be in order.

Proceed, Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Rakoff.

The CHAIRMAN. Your name and address first, Doctor.

Dr. RAKOFF. Abraham E. Rakoff, 269 South Nineteenth Street, Philadelphia, Pa.

(The oath was administered by the chairman.)

The CHAIRMAN. Mr. Kleinfeld.

TESTIMONY OF ABRAHAM E. RAKOFF, M. D., PHILADELPHIA, PA.

Mr. KLEINFELD. Dr. Rakoff, where did you obtain your medical degree?

Dr. RAKOFF. Jefferson Medical College, Philadelphia.

Mr. KLEINFELD. What year?

Dr. RAKOFF. In 1937.

Mr. KLEINFELD. And what is your specialized field?

Dr. RAKOFF. Endocrinology.

Mr. KLEINFELD. How long have you been specializing in that field?

Dr. RAKOFF. Twelve years.

Mr. KLEINFELD. Where are you located, sir?

Dr. RAKOFF. In Philadelphia, at the Jefferson Medical College, and I have my office at 269 South Nineteenth Street.

Mr. KLEINFELD. What is your association with the Jefferson Medical College?

Dr. RAKOFF. Clinical professor of obstetric and gynecologic endocrinology.

Mr. KLEINFELD. And you also conduct a practice in that field?

Dr. RAKOFF. I do.

Mr. KLEINFELD. Will you please read your statement?

Dr. RAKOFF. It is my opinion that cosmetics containing estrogenic hormones may produce undesirable effects under certain circumstances and should not be made available to the public except on prescription by the physician for the following reasons:

It is well-established that estrogens are absorbed through the skin and when given by this route can produce estrogenic effects on various tissues of the body. Estrogenic effects can result from the long-continued use of even small amounts of administered hormone. There are many circumstances in which the administration of exogenous estrogens is contraindicated. Long-continued administration with small amounts of estrogens may produce endometrial hyperplasia and uterine bleeding in postmenopausal women. The postmenopausal period in women is characterized by the gradual diminution in ovarian function and the withdrawal of estrogens. This results in regression of stimulation of many epithelial structures including the lining of the uterus, cervix, vagina, and the glandular tissue of the breast. The reactivation of these tissues may be accomplished by the administration of even small amounts of estrogens given over a long period of time. Under certain circumstances undesirable effects may result from such reactivation, particularly the induction of uterine bleeding. If uterine bleeding occurs, examination and sometimes operation, namely curettage of the uterus is necessary to determine the cause of the bleeding.

In patients who have fibroid tumors of the uterus, estrogens may stimulate their more rapid growth. It is generally agreed that estrogens are contraindicated in women with endometrial and cervical carcinoma. Estrogens even in the smallest dosage are contraindicated in many types of breast conditions, including some cases

of fibrocystic disease of the breast, benign tumors of the breast, and carcinoma.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. As I gather from your statement, Doctor, from the viewpoint of an endocrinologist, it is your opinion that a serious problem is raised by the use of estrogenic hormones in cosmetics; is that correct?

Dr. RAKOFF. That is correct.

Mr. KLEINFELD. And that possible danger exists because of what may happen to certain women in certain conditions; is that correct?

Dr. RAKOFF. That is correct.

Mr. KLEINFELD. Now, as I understand it from reading the literature and various advertising material put out by many manufacturers, it appears that estrogenic hormones are used in many different types of cosmetics now—for example, creams, oils, lotions, shampoos, and hair preparations—and they are recommended for use on various portions of the body: The face, the neck, the throat, hands, arms, scalp, and hair.

Now if many preparations contain estrogenic hormones and are applied to comparatively large areas of the body, does that accentuate the problem or not?

Dr. RAKOFF. It certainly does.

Mr. KLEINFELD. In what way, sir?

Dr. RAKOFF. Well, simply because the hormone will be absorbed from all of these various sites increasing the total absorption, the larger the surface area used; and therefore, the greater the effect on various tissues of the body in addition to those to which they have been applied.

Mr. KLEINFELD. And is the problem accentuated if the products are used during most of the hours of the day and night and for extended periods of time, for example, several months, or 6 months, or a year?

Dr. RAKOFF. I think that the factor of time is perhaps the most important single factor, because in the use of these hormones the long continued administration has a cumulative effect which is more undesirable than brief even though more intensive effects.

Mr. KLEINFELD. Now, I have an issue of the Western Journal of Surgery, Obstetrics and Gynecology, Volume 56, No. 9, September 1948. There was an article in there entitled "The Association of Estrogenic Administration and Adenocarcinoma of the Endometrium," by E. Malcolm Stokes, M. D., and here is what he says in part, and I quote:

> Undoubtedly, single large doses of estrogenic substances are quickly excreted and are unimportant in regard to carcinogenic activity. On the other hand, long continued, repeated administration of relatively small doses may intensify tissue response to the hormone. This is believed to be an important but infrequently emphasized phenomena.

Is that in general accord with the statement you just made?

Dr. RAKOFF. Yes.

Mr. KLEINFELD. That is your position also?

Dr. RAKOFF. Yes.

Mr. KLEINFELD. As I understand it, the ordinary cosmetic preparation containing hormones contains 20,000 international units for 30-day application, that is, for a 30-day supply.

Dr. RAKOFF. What was that dosage—10,000?

Mr. KLEINFELD. I think the ordinary jar contains for a 30-day usage, for a month's supply, I believe, 20,000 international units of hormones. It is 2 ounces, 10,000 per ounce.

Dr. RAKOFF. Yes; that is right.

Mr. KLEINFELD. Have you any idea what the rate of absorption might be?

Dr. RAKOFF. It is my clinical impression that the rate of absorption would fall somewhere between 20 and 50 percent.

Mr. KLEINFELD. So that fairly considerable amounts would be absorbed into the body?

Dr. RAKOFF. Yes; the rate of absorption, of course, would vary a great deal with the base used. It might be absorbed in larger amounts from some preparations than from others.

Mr. KLEINFELD. And if the cosmetic were rubbed vigorously into the skin, would that increase the rate of absorption?

Dr. RAKOFF. Yes, it would; and as a matter of fact, that type of administration has long been used therapeutically by physicians because it has been found to be more effective in introducing some estrogenic hormones into the body than even their administration by mouth.

Mr. MCDONOUGH. Mr. Chairman, will Mr. Kleinfeld yield?

Mr. KLEINFELD. Yes.

Mr. MCDONOUGH. Do you believe, Doctor, that legislation is necessary to draw a line between the use of estrogenic hormones for cosmetic purposes and for therapeutic purposes?

Dr. RAKOFF. I do, sir. I believe that estrongenic hormones should never be used or sold for cosmetic purposes without prescription.

Mr. MCDONOUGH. In any quantity?

Dr. RAKOFF. In any quantity.

Mr. MCDONOUGH. And with any type of base?

Dr. RAKOFF. With any type of base or in any quantity.

Mr. MCDONOUGH. In other words, estrogenic hormones in cosmetics is actually application for therapeutic value, but it is used for beautification. That is the way it is being used now—for beautification purposes?

Dr. RAKOFF. I believe that the use of estrogenic hormones should be prohibited without the use of prescription, because otherwise it is a dangerous mode of therapy.

Mr. MCDONOUGH. I see your statement confines itself to women in the postmenstrual period. What effect would it have on women who are not in that period?

Dr. RAKOFF. Only the second paragraph concerns postmenopausal women. The following paragraph, namely, that relating to fibroid tumors, would refer to younger women during the reproductive years, and so would the statements concerning diseases of the breast refer to women of any age.

Mr. MCDONOUGH. But do you think it is more dangerous to those in the post period than in the previous period?

Dr. RAKOFF. I think it is more likely to give rise to more frequent side-effects in the postmenopausal period.

Mr. MCDONOUGH. That category of women is more inclined to use these cosmetics than in the previous period?

Dr. RAKOFF. That is my impression.

Mr. MCDONOUGH. Would you explain and put in layman's language what you mean by endometrial hyperplasia?

Dr. RAKOFF. The endometrium is the lining of the uterus from which menstruation occurs. During the reproductive years that lining is built up each month and then breaks down and menstruation occurs. After the menopause, when the ovary stops working to a considerable degree, that lining becomes very thin, and therefore there is no menstruation. However, if one supplies the hormone that the ovary makes, namely, estrogens, then that lining will begin to build up again, and when it reaches a certain degree of development it will break down and bleeding will occur.

Mr. MCDONOUGH. Well, then, in other words, you think that in some instances where hormones aren't sufficient in young women, that the application of hormones is a good thing therapeutically?

Dr. RAKOFF. Yes.

Mr. MCDONOUGH. And that after a woman passes the period of reproduction, in the postmenstrual period, then the application of hormones is detrimental unless administered by a physician?

Dr. RAKOFF. Yes, it could be.

Mr. MCDONOUGH. Does the human system have a tendency to produce its own hormones to supply that need?

Dr. RAKOFF. It does. During the reproductive years, it produces goodly amounts; after the menopause, the amount decreases markedly.

Mr. MCDONOUGH. In other words, it can produce a surplus and do no harm to the human being?

Dr. RAKOFF. It can produce a surplus which may result in harm to a person even under normal circumstances.

Mr. MCDONOUGH. You mean the system itself can produce a surplus and do some harm?

Dr. RAKOFF. Yes.

Mr. MCDONOUGH. And if that is supplemented by the application of a cream containing them, or an oil, that could do added harm?

Dr. RAKOFF. Yes; that would aggravate the situation.

Mr. MCDONOUGH. Then do I understand from your statement also that in the postmenstrual period the tendency is to throw off the hormones, that is the system without any stimulant at all from the outside naturally throws off the hormones?

Dr. RAKOFF. It makes less.

Mr. MCDONOUGH. It makes less?

Dr. RAKOFF. Yes.

Mr. MCDONOUGH. And it needs less?

Dr. RAKOFF. And it needs less.

Mr. MCDONOUGH. That is all.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. No further questions.

The CHAIRMAN. Mr. Jones?

Mr. JONES. I am not saying this critically, but I note that you are expressing the opinion that these cosmetics should not be made available to the public except on prescription by the physician, and give your reasons.

Do you agree that in the past most physicians have recommended that many drugs such as aspirin, which are commonly sold and in general use, that the recommendations were made by physicians that they should be sold only upon a prescription and used as directed by physicians? Was that a fact?

Dr. RAKOFF. I believe that is so.

Mr. JONES. I don't intend to leave the impression that I am criticizing the medical profession for trying to preserve its position and dignity and everything that goes with it. But the thing I am interested in is to convince myself that this opinion of yours and other doctors—and I think you all agree the same way—whether you could be prejudiced in that view because of your profession.

Dr. RAKOFF. I do not believe that that is so. In my opinion hormones are more dangerous than most medications, particularly if used without proper knowledge by the public. There are many conditions in which even the physician would not give estrogens, based on his physical examination.

For instance, if you examined a patient and found that she had a fibroid tumor of the uterus, I am sure that every doctor would say that estrogens are absolutely contraindicated under those circumstances in any amount.

A patient who goes to the store and buys estrogenic creams may not know whether she does or does not have a fibroid tumor. She applies this substance, and she may aggravate her fibroid tumor; whereas, if she went to a physician and if he deemed it wise for her to use estrogen, it is generally agreed that he should not prescribe estrogens until he has done an adequate pelvic examination. That is the basis on which he would say that estrogens are or are not contraindicated.

Mr. JONES. Let's pursue it a little further. Is there a likelihood that a fatality might result from the use of an estrogenic cream?

Dr. RAKOFF. It is conceivable.

Mr. JONES. Well, is the likelihood greater that a fatality might result from that than from the use of, say, a bromide or an aspirin or a combination of drugs taken by someone with a heart condition, a drug that they can buy at any drug counter without a prescription?

Dr. RAKOFF. Probably not. However, I think that the untoward effects would be many, many times higher than from the use of aspirin or other such medicaments, but not necessarily a fatality. I think, for instance, that the instances of uterine bleeding, growth of tumors, and operations would be greatly increased.

Every month in our gynecologic service we see patients admitted to the hospital for an operation which we believe was due to the fact that they were obtaining estrogens over the counter without prescription and simply taking it on their own.

Mr. JONES. Yet at the same time, very frequently—I won't say every day—but very frequently we will read in the paper where someone has been found dead by taking an overdose of sleeping powder that they bought at the drug store; is that true?

Dr. RAKOFF. Yes. I think that is unfortunate.

Mr. JONES. I do, too.

That is all, Mr. Chairman.

Mr. KLEINFELD. I have another question.

The CHAIRMAN. All right.

Mr. KLEINFELD. Dr. Rakoff, do you know whether you can get sleeping pills without a prescription?

Dr. RAKOFF. I know that many patients do.

Mr. KLEINFELD. Well, it is illegal, of course.

Thank you, Doctor, very much.

The CHAIRMAN. The next witness.

Mr. KLEINFELD. Is the Maas & Waldstein Co. representative here?
Mr. MAGNUS. Yes.
The CHAIRMAN. Your name and address?
Mr. MAGNUS. Robert Magnus, 438 Riverside Avenue, Newark, N. J.
(The oath was administered by the chairman.)
The CHAIRMAN. Proceed.

TESTIMONY OF ROBERT MAGNUS, TREASURER AND FACTORY MANAGER, MAAS & WALDSTEIN, NEWARK, N. J.

Mr. KLEINFELD. What is your position with the Maas & Waldstein Co.?
Mr. MAGNUS. Treasurer and factory manager.
Mr. KLEINFELD. And what does the Maas & Waldstein Co. manufacture?
Mr. MAGNUS. Manufactures clear and colored nail lacquers, and also other materials for finishing industry.
Mr. KLEINFELD. To whom do you sell?
Mr. MAGNUS. To distributors——
Mr. KLEINFELD. I mean what classes of people do you sell to?
Mr. MAGNUS. To distributors of nail lacquers, manufacturers of industrial equipment.
Mr. KLEINFELD. Please read your statement.
Mr. MAGNUS. The statement that we submitted?
The CHAIRMAN. One second. We are interested in chemicals in cosmetics here. Did you say industrial machines?
Mr. MAGNUS. The statement which was submitted to the committee at their request refers to what we supply to the cosmetic industry.
The CHAIRMAN. All right, continue.
Mr. MAGNUS. Regarding materials referred to in this statement, I would like to request the committee to file it confidentially, as we feel it is our stock in trade.
The CHAIRMAN. All right, you don't have to mention them.
Mr. MCDONOUGH. If it is part of the record, it is not confidential.
Mr. MAGNUS. And not to be published, if possible.
The CHAIRMAN. We will reserve opinion on that. We will try to protect you as long as the request is in.
Mr. KLEINFELD. I understand, unfortunately, the statements have been put on the press table. I suggest then, if the chairman wants to, we can recall it.
The CHAIRMAN. You think it might injure you?
Mr. MAGNUS. Definitely.
The CHAIRMAN. It is not our intention to injure anyone. If those papers are available, we will pick them up.
Mr. KLEINFELD. May I suggest we do not put it in the record?
The CHAIRMAN. All right.
Mr. MCDONOUGH. Before the witness proceeds, let me understand the situation. You are here to inform the committee of the products that you manufacture, which you sell to the cosmetic trade?
Mr. MAGNUS. That is correct, sir.
Mr. MCDONOUGH. I don't see that is within the purview of the committee.
The CHAIRMAN. I think if we got together here on what this man has in mind—but he has a reason for making the request.

Mr. McDONOUGH. You mean the witness requested to testify?

The CHAIRMAN. No. Maybe one or two of these ingredients would be so simple that those people who buy from you would make it themselves?

Mr. MAGNUS. Right you are, sir.

The CHAIRMAN. And would destroy your business?

Mr. MAGNUS. Right, sir.

The CHAIRMAN. It is not our intention to destroy anybody's business.

Mr. McDONOUGH. What I am getting at, I don't think this committee is interested in the manufacture of materials that the manufacturer himself does not put in cosmetics. We are interested in the cosmetic people that use the stuff you produce and put it in various combinations and sell it to the public.

Do you sell over the counter?

Mr. MAGNUS. No; we don't.

We went one step further in answering your inquiry by giving it to you completely and fundamentally, so you knew exactly what was in it, and you as a committee could use it for your own benefit. But we didn't believe it would become public property.

Mr. KLEINFELD. They make a completed cosmetic product.

Mr. McDONOUGH. Do they sell it to the public?

Mr. KLEINFELD. No, but they make cosmetics.

Mr. McDONOUGH. I don't think it is in the purview of the committee, because we can go beyond him and find out where he gets the material that goes into his product. What I am talking about is a product that goes to the public over the counter and is bought promiscuously, and that is what the committee is organized and authorized to do.

The CHAIRMAN. Off the record.

(Discussion off the record.)

Mr. KLEINFELD. Does the committee want to hear him?

The CHAIRMAN. Yes.

Mr. KLEINFELD. Read your statement.

Mr. MAGNUS. We manufacture clear and colored nail lacquers and removers for sale to distributors or packagers.

The CHAIRMAN. Omit the ingredients and complete the statement.

Mr. MAGNUS. Chemical laboratory tests, originally to select and routinely for quality control, wear tests and patch tests are conducted by chemists and dermatologists to determine suitability for the service for which the products are intended.

There have been hundreds of millions of bottles of nail lacquers and removers marketed and the resultant incidence of allergenicity has been extremely minute.

We consider the present regulations of the Food and Drug Administration as being adequate for the protection of the Nation's health and safety.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. You manufacture nail lacquers and removers; is that correct?

Mr. MAGNUS. Yes, sir.

Mr. KLEINFELD. These are finished cosmetic products?

Mr. MAGNUS. Yes, sir.

Mr. KLEINFELD. Do you make any other types of cosmetics?

Mr. MAGNUS. We do not.

Mr. KLEINFELD. I want to get the course of business in which you are engaged. You make a nail lacquer which is a finished nail lacquer product; right?

Mr. MAGNUS. Correct.

Mr. KLEINFELD. Then you sell it to a cosmetic company which places its label on your products; is that correct?

Mr. MAGNUS. We sell it in bulk. They package and label it.

Mr. KLEINFELD. They take your product, your product intact; is that correct, and——

Mr. MAGNUS. Yes, sir.

Mr. KLEINFELD. And just put their label on it?

Mr. MAGNUS. I have to qualify that. We sell it in bulk. We don't sell in bottles.

Mr. KLEINFELD. Well, you sell it in bulk, they then put it in their own container, and put their own label on it?

Mr. MAGNUS. That is correct.

Mr. KLEINFELD. That is what ordinarily is done with your product?

Mr. MAGNUS. Correct.

Mr. KLEINFELD. So that colored nail lacquers or clear nail lacquers or removers which you make may be sold by a number of cosmetic distributors under different labels; is that right?

Mr. MAGNUS. Yes.

Mr. KLEINFELD. What chemical laboratory tests are performed by you on your products before you sell them?

Mr. MAGNUS. When we receive our raw materials—pardon me. You want me to start with the raw material right on through?

Mr. KLEINFELD. Start right from the beginning.

Mr. MAGNUS. When we receive our raw materials, we test them in our control laboratories. A sample is taken from the receiving room, given a receiving slip number, and the supplier's name of the material is on the receiving report; the sample goes to our laboratory for test. The specific specification tests for that particular raw material are conducted in the laboratory. If it meets all the specifications then it is coded and the report is sent to the receiving room and the particular shipment of material is then coded with our manufacturing code, and is ready for use in the factory.

Mr. KLEINFELD. Continue.

Mr. MAGNUS. We manufacture the clear or colored nail lacquers, and a manufacturing slip is written showing the quantities of the colors and ingredients to be used. The manufacturing slip is given to a production supervisor, and he supervises the manufacturing of the batch.

The ingredients, as I said, are all coded so that an employee doesn't work with chemical names which might be confusing to him. He also works with the receiving slip number. The receiving slip number becomes part of the raw material stock record. So that he has a double check on the material that he is taking for batch compounding.

When the material is completed it is sent to the laboratories for control tests to make sure that it meets the standards.

Do you want to know the tests run at that time?

Mr. KLEINFELD. Yes.

Mr. MAGNUS. The tests run are viscosity, film properties and brush-out, to make sure that it is up to standard.

Mr. MCDONOUGH. Inflammability?

Mr. MAGNUS. No.

Mr. MCDONOUGH. Melting point?

Mr. MAGNUS. Not in that instance. That is on the raw material side. I didn't go into the whole story on raw materials, each individual product, but I can.

Mr. MCDONOUGH. No, no. I am just talking about the finished product. It is not inflammable, the final product?

Mr. MAGNUS. Pardon?

Mr. MCDONOUGH. The final product is not inflammable?

Mr. MAGNUS. Not being a technical man, I don't want to give a definite answer. I think it is.

Mr. KLEINFELD. Do you have your own laboratory?

Mr. MAGNUS. Yes; we have our own laboratory.

Mr. KLEINFELD. What kind of personnel do you have?

Mr. MAGNUS. Graduate chemists.

Mr. KLEINFELD. How many?

Mr. MAGNUS. About 13.

Mr. KLEINFELD. Who else?

Mr. MAGNUS. And technicians.

Mr. KLEINFELD. Technicians?

Mr. MAGNUS. Also technicians.

Mr. KLEINFELD. Anybody else?

Mr. MAGNUS. In the laboratories?

Mr. KLEINFELD. Yes.

Mr. MAGNUS. Practical color matchers that standardize on colors or shades, which have nothing to do with this particular phase of the business.

Mr. KLEINFELD. Before you sell your product, what is done in your laboratory to assure your company that your product may not cause any damage to consumers?

Mr. MAGNUS. The nail lacquer is of the same type of formulae as were manufactured by us for many years and in controlling against a control standard we are sure that the product is safe because of its long usage.

Mr. KLEINFELD. But before you sell it, before you have the usage, what do you do to assure yourself that the products do not cause any untoward results?

Mr. MAGNUS. Well this product has proven itself by the number of years it has been on the market, and if we control to the standard, then it is considered as being acceptable for the market.

Mr. KLEINFELD. When did you first put out a product?

Mr. MAGNUS. You mean going back 20 years?

Mr. KLEINFELD. Have you put out any product in the last 20 years?

Mr. MAGNUS. Well, the product that we are marketing at present is a product that has been made of the same ingredients and subject to the same control for approximately 20 years.

Mr. KLEINFELD. All your products?

Mr. MAGNUS. All our products.

Mr. KLEINFELD. Well——

Mr. MAGNUS. There is a color shade difference. The colors we use are D & C colors.

Mr. KLEINFELD. How many products do you make?

Mr. MAGNUS. For the clear and colored nail lacquer industry, for the cosmetic industry—may I ask a question?

Mr. KLEINFELD. Surely.

Mr. MAGNUS. Do you want the number of colors we manufacture as products or are you now talking about different types of products?

Mr. KLEINFELD. I am talking about the different kinds of cosmetic products that you manufacture.

Mr. MAGNUS. Well, they are all so similar that I think I can say clear nail lacquers, colored nail lacquers, and removers are similar in their nature.

Mr. KLEINFELD. Do the formulas change from time to time?

Mr. MAGNUS. Slightly.

Mr. KLEINFELD. When was the last time you changed the formula?

Mr. MAGNUS. For color shades, within the last 2 months; for basic composition, the present colored and clear nail lacquers, I would say 15 to 20 years.

Mr. KLEINFELD. This change in formulation 2 months ago, in regard to that—— ·

Mr. MAGNUS. That change in color formula would be so slight it would be within the realm of the over-all picture of nail lacquer.

Mr. KLEINFELD. Well, who determines that?

Mr. MAGNUS. Our chemists in the laboratory.

Mr. KLEINFELD. Do you discuss the problem with a dermatologist at all?

Mr. MAGNUS. Not for this line of products because it was proven in the field.

Mr. KLEINFELD. Well, is it proven when you change your formula?

Mr. MAGNUS. I believe it is, because it is still within the same scope of formulation.

Mr. KLEINFELD. You say that chemical laboratory tests and wear tests and patch tests are conducted by chemists and dermatologists. When was the last time that one of your products was tested by a dermatologist?

Mr. MAGNUS. About 6 years ago.

Mr. KLEINFELD. Why did you consult a dermatologist?

Mr. MAGNUS. At that time, a new product was considered to be put on the market that we thought should be checked before we marketed it.

Mr. KLEINFELD. That was 6 years ago?

Mr. MAGNUS. Yes.

Mr. KLEINFELD. Not 20 years ago?

Mr. MAGNUS. No; that is right.

Mr. KLEINFELD. Six years ago, what product did you put out?

Mr. MAGNUS. It must be more than 6 years ago—8 years ago. We put out a new base coat.

Mr. KLEINFELD. Base coat. And you consulted a dermatologist?

Mr. MAGNUS. That is correct.

Mr. KLEINFELD. Before you put it out?

Mr. MAGNUS. Yes, sir.

Mr. KLEINFELD. What did he tell you about it?

Mr. MAGNUS. He said it was satisfactory for use.

Mr. KLEINFELD. Is that the product which caused injury to users?

Mr. MAGNUS. I couldn't answer that, because when you say "the product"——

Mr. KLEINFELD. Let me put it this way——

Mr. MAGNUS. That brings it to one product.

Mr. KLEINFELD. Did you make a nail undercoat which you sold to a number of cosmetic distributors which resulted in some injuries to users—I am not saying it was anybody's fault—and which ultimately was recalled by these distributors? Are you familiar with that episode at all?

Mr. MAGNUS. Yes; I am. There was a product on the market that we sold——

Mr. KLEINFELD. Go right ahead. It was your product that was involved in these recalls?

Mr. MAGNUS. Our product that was? Would you repeat your question, please?

Mr. KLEINFELD. Have you ever made a nail undercoat?

Mr. MAGNUS. Yes; we have made a nail undercoat.

Mr. KLEINFELD. Was that the product you marketed about 8 years ago?

Mr. MAGNUS. That is correct.

Mr. MCDONOUGH. You had better identify this by brand name. What are we talking about?

Mr. KLEINFELD. To whom did you sell the product?

Mr. MAGNUS. We sold the product to Revlon.

Mr. KLEINFELD. Who else?

Mr. MAGNUS. Durlin.

Mr. KLEINFELD. Who else?

Mr. MAGNUS. That is all.

Mr. KLEINFELD. Just those two?

Mr. MAGNUS. Correct.

Mr. KLEINFELD. Were products you manufactured put out under their trade names?

Mr. MAGNUS. I imagine they did. They were not under our trade names.

Mr. KLEINFELD. Is Durlin a subsidiary of your concern?

Mr. MAGNUS. No; an affiliate.

Mr. KLEINFELD. Affiliate?

Mr. MAGNUS. Yes.

Mr. KLEINFELD. Now, does Durlin sell to others?

Mr. MAGNUS. Yes.

Mr. KLEINFELD. To other cosmetic manufacturers?

Mr. MAGNUS. I believe they do. Should I answer questions in regard to Durlin at this hearing?

Mr. KLEINFELD. If you know. If you don't, say so.

Do you know to whom Durlin sold your product?

Mr. MAGNUS. I would prefer to give a list to the committee after I refer to the records, because it goes back 8 years.

Mr. KLEINFELD. I have a paper here which lists some of the cosmetic distributors among whose products is included the nail undercoat which did damage to a number of users.

Did you sell to the Nailast Co., in Hollywood, Calif.?

Mr. MAGNUS. I don't recall the name.

Mr. KLEINFELD. Do you know whether Durlin, your affiliate, did?

Mr. MAGNUS. I don't recall the name either way.

Mr. KLEINFELD. How about Schnefel Bros. Corp.?

Mr. MAGNUS. Yes; I believe Durlin did.

Mr. KLEINFELD. And Roux Distributing Co.?

Mr. MAGNUS. Roux?

Mr. KLEINFELD. Some Roux Co.?

Mr. MAGNUS. Yes.

Mr. KLEINFELD. How about the Perma-Nail Co., of Burbank, Calif.?

Mr. MAGNUS. No; definitely no.

Mr. KLEINFELD. Revlon Products?

Mr. MAGNUS. Yes.

Mr. KLEINFELD. So these are some of the companies to whom you or your affiliate sold this product, and it was this product that was involved in the recall initiated after there had been some damage caused; is that right?

Mr. MAGNUS. Before we put out our products of that type there was a product on the market that had apparently been successful. Other distributors wanted it, and that is why we marketed that type of product.

Mr. KLEINFELD. You conclude your statement by saying as follows:

> We consider the present regulations of the Food and Drug Administration as being adequate for the protection of the Nation's health and safety.

Now I have a letter here which the committee received from the Food and Drug Administration——

Mr. MAGNUS. After being—pardon me.

Mr. KLEINFELD. Pardon me. Go ahead.

Mr. MAGNUS. After being at this hearing, I think that something should be done in order to protect the public and the manufacturer both.

Mr. KLEINFELD. You mean you want to change your statement?

Mr. MAGNUS. Well, as it stands, I think the Food and Drug Administration has the authority to put any necessary controls in, and I think if they put the necessary controls in, that they could well administer the job.

Mr. KLEINFELD. Well, let me read to you a report which this committee received from the Food and Drug Administration and get your reaction to it. Here is what the Food and Drug Administration told this committee:

> About 4 years ago numerous complaints were received from women whose fingers had been significantly injured as a result of using lacquers marketed in the form of fingernail coating. Again the ingredients employed were different kinds of newly developed products related to synthetic rubber, and no adequate testing was undertaken prior to marketing the coatings to determine whether they might have any propensity for injury. These products are exceedingly complex organic chemicals more in the nature of mixtures than specific entities, and the only practical approach to evaluating their properties for harm is adequate tests on lower animals or human beings. Because of the complex chemical character of the ingredients it was very difficult to determine the precise nature of the offending constituent, and it became necessary to regard each batch or lot as an entity unto itself and to undertake individual testing. Again lack of adequate pretesting and experimenting on the public with unknown chemicals resulted in substantial injury to many users of this type of cosmetic. Finally, by belated study and experimentation, manufacturers were able to produce satisfactory articles without deleterious ingredients.

Isn't the Food and Drug Administration here talking about the product which you sold to the companies whose names we mentioned a few minutes ago?

Mr. MAGNUS. Unless it so specifically states, I wouldn't want to assume that it was referring to our product.

Mr. KLEINFELD. Well, it was your product sold to several concerns which did result in some injury; is that not so? You may say that you couldn't forsee it, but there were injuries, were there not?

Mr. MAGNUS. There were instances of allergy. I don't like the word "injury," because I can't define it.

Mr. KLEINFELD. Can you define allergy?

Mr. MAGNUS. No; not after being here.

Mr. KLEINFELD. Let's use any term we want. But some people were hurt; is that not so?

Mr. MAGNUS. That is right. But I take exception to the statement no tests were made in this report, if they are referring to our product. Does it say they are referring to our product or products of our manufacture?

Mr. KLEINFELD. No.

Mr. MAGNUS. Because tests were made on our product before it was marketed.

Mr. KLEINFELD. I suppose it is a question of definition whether the tests you made were adequate tests, if the product hurt somebody.

Mr. MAGNUS. Well, we believe that prudent, adequate tests were made before our product was marketed.

Mr. KLEINFELD. Did any of your customers talk to you or write to you about the nail undercoat which you sold to them and which resulted in complaints from their customers because of injuries received?

Mr. MAGNUS. Yes.

Mr. KLEINFELD. So, in fact, there were injuries, weren't there?

Mr. MAGNUS. When you say "injuries," I want to qualify that again—it was an allergic manifestation of some kind—because injury, shall I say, is a long word.

Mr. KLEINFELD. Let's use a shorter word. What would you say happened to these women?

Mr. MAGNUS. May I ask a question on the date of that report that you read?

Mr. KLEINFELD. The report is dated September 13, 1951.

Mr. JONES. I want to clear up one thing here. You said a minute ago that others were putting out a base coat and your customers were demanding such a thing and that is the reason you went into this particular formula; is that correct?

Mr. MAGNUS. That is correct.

Mr. JONES. Now at the time you changed the formula and put out the new formula, did you have tests made for the new formula?

Mr. MAGNUS. Yes, sir; we did.

Mr. JONES. Had you had complaints that the old formula was not satisfactory and did the people to whom you sold it demand that you replace it with another product?

Mr. MAGNUS. We were called by one of our customers. We had a consultation. They had been in touch with Government and medical authorities, and wanting to be prudent they took the material off the market and we stopped manufacturing it.

Mr. JONES. Did you replace the material they took off the market with a similar product?

Mr. MAGNUS. No.

Mr. JONES. Did you compensate them for the material?

Mr. MAGNUS. No. The product that you are referring to is the base coat that Mr. Kleinfeld is referring to?

Mr. JONES. The same one.

Mr. MAGNUS. So that I keep my "yesses" and "noes" on the right line, because it is a very narrow subject when you say base coat, because we are presently marketing base coats which are old-time base coats.

Mr. JONES. I don't think there is any misunderstanding here. I think we understand each other. I think you understand that the Food and Drug Administration did find fault with a base coat that was distributed by several companies.

Mr. MAGNUS. That is correct.

Mr. JONES. Did your company manufacture one of those that was complained of?

Mr. MAGNUS. I believe we did; yes.

Mr. JONES. And then you later changed the formula?

Mr. MAGNUS. We went back to the original formula.

Mr. JONES. You are not now making the formula they complained of?

Mr. MAGNUS. We have not for 6 or 8 years.

Mr. JONES. Do you agree that there is something wrong with the formula that the Food and Drug complained of?

Mr. MAGNUS. Not being a technical man, my answer will be "No," because—and I will have to qualify it—tests were made before it was marketed and it didn't show any difficulties. We made tests, I will say hundreds, and there was no allergenicity or allergenic manifestations or anything. It seemed perfectly all right.

Mr. JONES. Am I to take it from that you would deny that your product caused any woman to lose her fingernails?

Mr. MAGNUS. I haven't seen it, so I can't deny or say "Yes." I have heard they have lost their nails, but I heard they have grown back without any trouble.

Mr. JONES. Am I correct in assuming now that the reason you manufactured this base coat which the Food and Drug made a complaint about, the reason that you put out that particular formula, was to meet a competitive demand?

Mr. MAGNUS. Correct.

Mr. JONES. That is right?

Mr. MAGNUS. But they didn't make any complaint to us.

Mr. JONES. But there is nothing on the label of these bottles or containers in which it is sold to indicate it is manufactured by Maas and Waldstein, is there?

Mr. MAGNUS. No.

Mr. JONES. So they would have no way of making direct complaint to you, because it would have Jones' or Kleinfeld's or some other company's name on there, and they would have no way of tracing it back to you except by inquiring of the company you supply.

Mr. MAGNUS. Right.

Mr. JONES. It would be reasonable to assume they did not come to you because they did not know you made it, would it not?

Mr. MAGNUS. Pardon me?

Mr. JONES. Would it not be reasonable to assume the reason the Food and Drug didn't complain to you or make request to you was because they did not know you made the product?

Mr. MAGNUS. It is reasonable to so assume.

Mr. JONES. I think that is all.

Do you have a question, Mr. McDonough?

Mr. MCDONOUGH. Well, the responsibility to the public is to the party that puts the label on the bottle and sells it to the public, is it not?

Mr. MAGNUS. I don't feel I am qualified to answer that one.

Mr. MCDONOUGH. Let me ask you this, then. Do you know whether the competitive firm that made the product that you made to meet the competition, were they also called in by the Food and Drug Administration?

Mr. MAGNUS. I couldn't answer that; I don't know. The first I heard of them was Mr. Kleinfeld reading from the letter of September 13, 1951.

Mr. MCDONOUGH. Was it during 1951 you had complaints?

Mr. MAGNUS. No, it was at least 6 years ago.

Mr. JONES. This letter said they had complaints 4 years ago from the date of that letter, did it not, Mr. Kleinfeld?

Mr. MAGNUS. Four years prior to September 1951, I take it.

Mr. KLEINFELD. About 4 years ago; yes.

Mr. MAGNUS. It is hard for me to determine whether they are talking about the same thing we are talking about or not.

Mr. MCDONOUGH. Do you carry insurance for deleterious effects of your products to the public or any user, any protecting insurance?

Mr. MAGNUS. We have insurance; yes.

Mr. MCDONOUGH. Is it insurance for that purpose?

Mr. MAGNUS. The insurance is for over-all purposes, to protect our corporate entity, not specifically for any one purpose. We do carry products liability insurance.

Mr. MCDONOUGH. Products liability insurance?

Mr. MAGNUS. That is right, with other types of insurance.

Mr. MCDONOUGH. Would that cover any case of anyone using your product and being injured?

Mr. MAGNUS. That I couldn't answer either without referring to the policy. That is what it should protect us against, yes. But that protection certainly isn't looked at by us as being our responsibility to our customers. We have been in business about 75 years and we certainly don't want to sell any products that are going to hurt either ourselves or our customers.

Mr. MCDONOUGH. Have you been making this kind of a product for 75 years?

Mr. MAGNUS. We've made nail lacquer about 30 years.

Mr. MCDONOUGH. What do you make besides nail lacquer?

Mr. MAGNUS. Industrial finishes.

Mr. MCDONOUGH. Industrial finishes?

Mr. MAGNUS. That is right. That part of the business has nothing to do with the business of this inquiry.

Mr. MCDONOUGH. This is in addition to your normal industrial finishes?

Mr. MAGNUS. That is right.

Mr. MCDONOUGH. Which is varnishes and lacquers of all sorts?

Mr. MAGNUS. Right.

Mr. MCDONOUGH. For wood and metal?

Mr. MAGNUS. Correct.

Mr. McDONOUGH. Is that the majority of your business?

Mr. MAGNUS. I prefer not to answer that, if I may be excused. I don't want to make our business public.

Mr. McDONOUGH. Do you make any other product? Of course, industrial lacquers and wood and metal lacquers have nothing to do with——

Mr. MAGNUS. Cosmetics.

Mr. McDONOUGH. Have nothing to do with cosmetics. In other words, because of the similarity of the product, a protective coating that is used on wood and machinery, you got into the cosmetic business for protective coating on human nails, is that the point?

Mr. MAGNUS. It sounds reasonable, but I can't go back to the early years and say "Yes" or "No."

Mr. McDONOUGH. Then are similar ingredients used for the protective coatings?

Mr. MAGNUS. There are some common ingredients used and certain dissimilar ingredients used also. I mean it is a different type of industry entirely.

Mr. McDONOUGH. Made in the same factory, however?

Mr. MAGNUS. In different buildings in the factory, in different sections of the factory, not in the same department.

Mr. McDONOUGH. Is that the only cosmetic you manufacture?

Mr. MAGNUS. Yes, clear and colored nail lacquers and removers.

Mr. McDONOUGH. You don't sell any to the public. You sell to distributors and they put their label on and they are responsible people to the public?

Mr. MAGNUS. Well, we have a responsibility. We don't assume——

Mr. McDONOUGH. What responsibility do you assume?

Mr. MAGNUS. Responsibility for definitely testing the raw materials, which we do, to make sure they are up to specifications, making sure that our finished product is up to specifications.

Mr. McDONOUGH. Specifications of what?

Mr. MAGNUS. Our own specifications for materials so that they are free from possible harm. That is what we try to do, and I think our experience has shown that we have succeeded by the number of millions of bottles that have been sold using these ingredients.

Mr. McDONOUGH. Do you make any of the cosmetic lacquer finishes for nails to the specifications of your customer, or do you make it according to your own formula alone?

Mr. MAGNUS. You say, do we?

Mr. McDONOUGH. Yes.

Mr. MAGNUS. No.

Mr. McDONOUGH. I mean if I were in the distributing business and wanted you——

Mr. MAGNUS. I don't think we would do it for you.

Mr. McDONOUGH. You would not?

Mr. MAGNUS. I don't think so.

Mr. McDONOUGH. You don't do that as a customary business?

Mr. MAGNUS. No, we don't because too many complications can arise if we just go ahead promiscuously and make materials to a manufacturer's specifications. We have been requested many times to make a lot of things industrially that we wouldn't make either.

Mr. McDONOUGH. And you think that the Food, Drug, and Cosmetic Act and the Administration has sufficient authority to protect the public if they use all the authority they have?

Mr. MAGNUS. They would have to set up a definite program so that there was assurance of protection to the public. What that should be, I don't want to voice an opinion, because there are many men that are better equipped that have been here at these meetings, and I have just begun to become acquainted with the broad scope of the Food, Drug, and Cosmetic Act. It seems far afield when we start talking about finishes and cosmetics.

Mr. MCDONOUGH. In other words, you are not certain then that the Administration has sufficient authority to cover the protection of the health and safety of the public? You are not certain of that?

Mr. MAGNUS. Well, I will put it in the affirmative. We should have something in the law to protect both the manufacturer and the consumer. If this law doesn't do it, or if these rules don't do it, then we should have rules to give that protection.

However, I think in our own case, and having been in business the number of years we have, we operate prudently so that we try to keep ourselves out of trouble. We have known manufacturers to start up overnight and market a product and get into trouble, and see them disappear within a few months after hurting the industry considerably. Because every time you do put out a product that is injurious it does hurt the market.

Mr. MCDONOUGH. The whole industry?

Mr. MAGNUS. That is right.

Mr. MCDONOUGH. Thank you.

Mr. JONES. Is that all, Mr. Kleinfeld?

Mr. KLEINFELD. Yes.

Mr. JONES. Thank you, Mr. Magnus.

Mr. KLEINFELD. Dr. Wolcott.

Mr. JONES. State your name and address.

Dr. WOLCOTT. George L. Wolcott, Bristol-Myers Co., 630 Park Avenue, New York City.

(The oath was administered by the chairman.)

Mr. JONES. Proceed.

TESTIMONY OF GEORGE L. WOLCOTT, M. D., MEDICAL DIRECTOR, BRISTOL-MYERS CO., NEW YORK, N. Y.

Mr. KLEINFELD. Do you have a prepared statement on behalf of the Bristol-Myers Co.?

Dr. WOLCOTT. I do.

Mr. KLEINFELD. Please read it.

Dr. WOLCOTT. The statement is in two parts. The first part of it was prepared by Dr. Dan Dahle, who is our director of research. That is product research.

Mr. KLEINFELD. Is Dr. Dan Dahle here?

Dr. WOLCOTT. He is not, sir.

Mr. KLEINFELD. I do not think we ought to accept that statement. It is certainly the customary procedure of this committee to ask witnesses who prepare statements to read them. Our wire to your company requested that a company representative appear to read a prepared statement.

Your reply to us said,

Bristol-Myers will be represented by Dr. George Wolcott.

Now I am glad to have you read your statement, but I think if Dr. Dan Dahle wants to read his statement he ought to be here.

Dr. WOLCOTT. It is up to you, sir.

Mr. JONES. You are Dr. Wolcott?

Dr. WOLCOTT. I am.

Mr. KLEINFELD. He has his statement here and another by Dr. Dahle.

Mr. JONES. Do you want to take his statement?

Mr. KLEINFELD. If he wants to give it, I will take it.

Dr. WOLCOTT. That is what I am here for.

Mr. KLEINFELD. You may read your own statement.

Dr. WOLCOTT. Do you wish me to include my qualifications?

Mr. KLEINFELD. Yes.

Mr. MCDONOUGH. I think the qualifications are acceptable.

Dr. WOLCOTT. At what point would you like me to begin, sir?

Mr. KLEINFELD. I suggest his qualifications should be put in the record.

Mr. JONES. I do not see any use of reading until you get down below here [indicating].

Mr. KLEINFELD. Beginning, "During my association."

Dr. WOLCOTT. I think before we leave the subject of this statement, I would like to have the record show that the original conference in our company was with Mr. Robert Brown, president, Dr. Dan Dahle, and myself present. Mr. Brown discussed your request with us, and asked Dr. Dahle and me to prepare a statement, and designated me to represent the Bristol-Myers Co. at this meeting. It was not our understanding that both men were to be present, nor did your telegram so state.

Mr. KLEINFELD. You must realize the difficulty. Are you in a position to answer questions based on a statement made by somebody else?

Dr. WOLCOTT. I don't know. It depends on what the questions are.

Mr. KLEINFELD. That is the difficulty, Doctor. We can't ask you questions on statements which you did not make.

Dr. WOLCOTT. I think the committee should understand our attitude in this. If you want Dr. Dahle here, I am sure we can get him here next week or at your convenience.

Mr. KLEINFELD. You are one of perhaps 30 or 40 companies to whom we wrote. Apparently they all understood we asked them to send a representative to testify, and what they did was send a statement signed by a representative and the representative then comes here and reads the statement. If you were laboring under a misunderstanding, it is unfortunate, sir. Please read your own statement.

Mr. JONES. I think it is all right, Mr. Kleinfeld, for this gentleman to give his statement and answer the questions and then we can decide whether we want Dr. Dahle to come.

Mr. KLEINFELD. I asked Dr. Wolcott to read his statement.

Mr. JONES. All right.

Dr. WOLCOTT. This is purely my own statement?

Mr. KLEINFELD. That is right.

Dr. WOLCOTT. Medical supervision of Bristol-Myers products——

Mr. JONES. Let's see. Suppose we start the first page with "During my association with Bristol-Myers."

Dr. WOLCOTT. That is part of the qualifications, sir.

Mr. JONES. I would like to get it in the record. Read the paragraph on the first page.

Dr. WOLCOTT. I think I will go back and start with my medical degree obtained in 1938, obtained from Columbia University, College of Physicians and Surgeons:

From 1938 to 1940, I was intern in Bellevue Hospital, in this city.

During 4 months of 1940, was advisory medical officer to the Federal Trade Commission in Washington, D. C.

From 1940 to 1942 I was medical director of Charles H. Phillips Co. division, Sterling Drug, Inc.

From 1942 to 1946, I was medical officer in the United States Army.

From 1946 to the present time I have been with Bristol-Myers Co., with which I have the present title of medical director, Bristol-Myers products division; director of industrial health, Bristol-Myers and subsidiary companies.

Medical licensure: State of New York, 1939; State of New Jersey, 1940.

Publications: One, Dangers in the Use of Cosmetics—a review of the medical literature—Archives of Dermatology and Syphilology 41:64–77, January 1940; two, Azotemia, Acidosis, Anemia, and Leukocytosis Following Sulfanilamide Therapy, New International Clinics, volume II, series 4, 1941, J. B. Lippincott Co.

During the period 1939 to 1946 I was a member of the editorial staff of Digest of Treatment, a monthly medical publication of the J. B. Lippincott Co., Philadelphia.

As an advisory medical officer to the Federal Trade Commission, I prepared scientific opinions on the advertising of foods, drugs, cosmetics, and therapeutic devices.

During my association with Bristol-Myers Co. I have enjoyed various position titles, leading to the present ones listed above. My responsibilities, however, consistently have been concerned with (1) medical supervision of products, including clinical research problems; (2) promotion of Bristol-Myers products to the various professional groups; and (3) supervision of plants' physicians and nurses concerned with maintaining and improving health of employees.

Medical supervision of Bristol-Myers products: In the Bristol-Myers products division we maintain a medical department, one of whose functions is the critical evaluation of any material which is under consideration for addition to an existent or new product. Reviews of all such materials are made with strict regard to any unpleasant or harmful toxic reactions which might attend human usage of the materials.

Our medical department includes a licensed physician and a pharmaceutical chemist, both of whom serve on a full-time basis. In addition, the department makes regular use of a staff of consulting specialists from the fields of dentistry, dermatology, gastroenterology, internal medicine, and pharmacy.

The review of proposed new ingredients initially is an exhaustive study of the scientific literature which describes known experience, especially clinical, with the material. In many cases this review provides sufficient information to evaluate its safety.

When this study of the literature does not give adequate data about the safety of a proposed new ingredient, an actual clinical evaluation

of the material is made under careful supervision and under actual conditions of use. Such clinical studies are conducted at university clinics and hospitals or under the direct supervision of practicing physicians. In exceptional cases, where little might be known about a new material and where its chemical structure is similar to better-known substances with some aura of potential hazard, animal toxicity tests would be required before release of these materials for human clinical evaluation.

Our medical review of product ingredients also is concerned with possible allergic side effects as well as the more serious but much more infrequent other forms of unpleasant toxic effects. For example, during the past 5 years we have made an extensive dermatologic study of all our products which are applied to or which may come into contact with the skin. Literally thousands of patch-test studies of our products were made on human subjects, and quite happily these tests demonstrated that our products were remarkably free of allergenic or sensitization properties. Subsequent to those tests, our medical department has required comparable data on proposed new ingredients before authorizing their use.

Mr. JONES. You may question, Mr. Kleinfeld.

Mr. KLEINFELD. Doctor, does Bristol-Myers submit its products to the Committee on Cosmetics of the American Medical Association?

Dr. WOLCOTT. We do not.

Mr. KLEINFELD. On the second page of your statement you say that the review of proposed new ingredients initially is an exhaustive study of the scientific literature.

Dr. WOLCOTT. Yes, sir.

Mr. KLEINFELD. Who makes that study for you, sir?

Dr. WOLCOTT. There may be a number of people concerned with it. We maintain two libraries, one a medical library here in New York, the other a chemical library in our plant at Hillside, and there are two librarians in each, especially trained, who hold no other technical degrees. They very often will secure the original articles for me or for Dr. Dahle or members of our staff, and we will read the article and make our own opinion on that basis. It is not left to the librarian to abstract or judge the article, that is left to some technical person like myself or Dr. Dahle.

Mr. KLEINFELD. And when you do not get adequate data from this study, an actual clinical evaluation of the material is made under careful supervision and actual conditions of use; is that correct?

Dr. WOLCOTT. Yes.

Mr. KLEINFELD. Who makes the actual clinical evaluation?

Dr. WOLCOTT. Probably one or more of the special consultants that are referred to in the second paragraph.

Mr. KLEINFELD. Who are these special consultants?

Dr. WOLCOTT. At the present time, the dermatologist is Dr. Irving Shapiro of Newark, N. J. In the past we have had the privilege of using Dr. Eugene Traub here in New York, Dr. Herbert Spoor, Dr. Charles Rien. In the field of gastroenterology, we have Dr. W. D. Paul, University of Iowa. Probably of no interest to the committee; that is more in the medical line of products.

In dentistry we have a number of consultants—Dr. Irving Glickman of Tufts Dental College in Boston; Dr. Thomas Hill of Western Reserve University in Cleveland, who is also chairman of the council on

dental therapeutics of the American Dental Clinic; Dr. Basil Bibby of Eastman of the Eastman dental dispensary; and Dr. Finn Brudevold.

Mr. KLEINFELD. Are you through, Doctor?

Dr. WOLCOTT. Yes.

Mr. KLEINFELD. And you say in exceptional cases animal toxicity tests would be required by your company before release of the material?

Dr. WOLCOTT. Yes.

Mr. KLEINFELD. Who would make those animal tests?

Dr. WOLCOTT. Probably an outside laboratory specially equipped to handle animal toxicity tests, both of acute and chronic nature.

Mr. KLEINFELD. Would they have a pharmacologist?

Dr. WOLCOTT. Oh, yes.

Mr. KLEINFELD. Go ahead.

Dr. WOLCOTT. On one or two occasions for small projects, we have used the facilities of our subsidiary Bristol laboratories in Syracuse, who maintain an animal house. Usually we try to avoid that, because they are so overburdened with their own activities, they don't like to do favors for us.

Mr. KLEINFELD. That laboratory employs pharmacologists?

Dr. WOLCOTT. Oh, yes.

Mr. KLEINFELD. You also say your medical review of product ingredients is also concerned with possible allergic side effects. In other words, that is something you take into consideration?

Dr. WOLCOTT. Yes.

Mr. KLEINFELD. And you also make, you say, literally thousands of patch test studies of your product.

Dr. WOLCOTT. That we have done in the past 5 years. That was a special project which was done under the direction of Dr. Traub. Each of our products that was used on the skin or regularly came in contact with the skin, even though that was not the primary use—for example, the dentifrice, where it is difficult to brush the teeth without having some toothpaste contact the skin of the upper or lower lip. So they made a study on Ipana, even though they intended it for use in the mouth, and every product of that nature. I think two or three thousand patch tests were done on that product, and there were repeat tests done after a period of 3 weeks to measure development of sensitization as well as primary allergies that might exist.

Mr. KLEINFELD. So you make patch tests for both reasons—to find out whether there are any direct irritants or any product which might cause observable allergic reactions?

Dr. WOLCOTT. That is right.

Mr. KLEINFELD. Who makes these patch tests for you, Doctor?

Dr. WOLCOTT. A dermatologist.

Mr. KLEINFELD. Are these patch tests made before a product is released commercially?

Dr. WOLCOTT. In this case these were done on existing products; in other words, our complete line of products. We made a special study at that time. So those were not done in advance.

Mr. KLEINFELD. Why was that?

Dr. WOLCOTT. I don't know exactly why it was started. I can only venture a guess that it was just to find out if we had any special irritant substances in our products and if there were any, to take such steps as might be best to replace them.

Mr. KLEINFELD. You do think, however, that performing those patch tests is an advisable thing to do?

Dr. WOLCOTT. I think it is very advisable to do where there is no history as to the allergenic nature of the product or of certain ingredients in the product. In other words, if there is a good background, if the chemical or ingredient is well-known and has been tested, I see no point in repeating it. But where you may be dealing with a brand new chemical or one which has not been adequately tested, I think it is incumbent upon the manufacturer to find out before he markets that product.

Mr. KLEINFELD. What about the situation where you may have two ingredients, each of which may perhaps have been well tested, but where the combination has not been—should not all these tests be made on the completed product?

Dr. WOLCOTT. I don't think that question can be answered "yes" or "no," for this reason: Potentiation of one product by another occurs in the drug field. In other words, you may have two products that alone will relieve pain; you put them together and something happens whereby the sum total is greater than the addition of both actions separately. That is called potentiation or synergism.

I am not familiar with any such situation which works with respect to harmless ingredients. In other words, if two ingredients are harmless and are known to be harmless in regular usage, a mere act of mixing them together, provided a new chemical is not formed, causes me not to suspect that you will incur any danger from the use of that mixture.

Mr. KLEINFELD. Suppose you were employing in your product a wetting agent which in itself had been shown to be harmless, and you were also employing some other product, let's say, a quaternary compound which in itself was known to produce no harmful effects. If you put those two substances together, might not that harmless wetting agent, harmless in itself, have such an effect upon the quaternary compound as far as penetration or absorbability is concerned that a new problem might be created?

Dr. WOLCOTT. Frankly, I don't know.

Mr. KLEINFELD. You don't make any shampoos, Doctor?

Dr. WOLCOTT. No.

Mr. KLEINFELD. In any event, you believe that Bristol-Meyers is conducting very thorough and exhaustive testing before it puts products on the market?

Dr. WOLCOTT. I do.

Mr. KLEINFELD. Do you believe that such testing is necessary?

Dr. WOLCOTT. Well, I certainly think it is necessary to the success of that company.

Mr. KLEINFELD. Do you think it is necessary to protect the public?

Dr. WOLCOTT. I think in general, yes. I hesitate on that, because again it goes through a lot of ramifications. There are many cases in this industry where I think little need be done. There are other cases where new ingredients are being utilized and adequate pretesting is not done. That is the field where I think a better regulation is necessary.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. What do you think ought to be done to improve the situation? You have no suggestions in the statement as far as I see it.

Dr. WOLCOTT. I have given that a lot of thought. In fact, I had hoped to append a statement here as to what I thought should be done and, after several hours, I gave up. Frankly, I think one phase of it is trying to legislate against human error. In this cosmetic industry certainly I think a problem common with every company is making good products that will successfully sell, and the consumer is a mighty critical individual. If you put out a product that is going to hurt him, he is going to be mad at that product, he is going to be mad at the company. And it is interesting in that regard to compare the same thing in medicine.

Mr. ABERNATHY. May I interrupt right there. It is also true the news gets around pretty fast, too?

Dr. WOLCOTT. It certainly does.

I might say at Bellevue in the early days of sulfa drugs a circus performer came in with a sore throat, hemolytic streptococcus, and was pretty sick. I was house physician at the time and prescribed sulfanilamide for him. In 24 hours the high fever disappeared and he was much better. Three days later he was a lot sicker because he had a very unusual reaction to the sulfa drug, something which you could not have discovered by pretesting. He had a strange kidney reaction where the material precipitated in the kidney and dozens of things happened thereafter. He was in the hospital for 3 months. There were times when we wondered whether he was going to walk out or be carried out.

That situation was in medicine. He was not mad at me as a physician, he was not mad at the hospital, he was not mad at the drug, because when a person is sick they will put up with some of these side effects. But with a cosmetic product, if something happens to them which they don't expect to happen when they are feeling well, they are good and mad.

Mr. HORAN. May I make a short statement, Mr. Chairman, which I think is to the point.

This committee is searching for a possible right amendment to the food and drug law, and we will do nothing, though, if we do not protect the producer as well as the consumer.

Dr. WOLCOTT. Yes.

Mr. HORAN. Our recommendation, of course, will go to a regular committee of Congress and hearings will be held on anything we might recommend in the form of a bill. I wish personally that the industry would be thinking about this and working in that field, and out of that we might improve the situation and guard against this human error that does exist.

Dr. WOLCOTT. We could be very selfish ourselves, and say that additional legislation which might result from this action probably will not disturb our pattern, nor will it inconvenience us by way of expense. I think we must recognize that the small fellow who can't afford a staff such as we have, because his business isn't big enough, may not be able to meet some of these rigid requirements.

I think the second witness this morning had a very splendid idea of possibly applying the regulation or any change in regulations to new substances about which there is no toxicological background. That is probably one of the fields today where we are getting into

trouble, where people are taking something new and not bothering to test it.

The CHAIRMAN. That is all. Thank you.

We will take a short recess.

(Short recess.)

The CHAIRMAN. The next witness.

Mr. KLEINFELD. Dr. Powers.

The CHAIRMAN. Your name and address, Doctor.

Dr. POWERS. Donald H. Powers, 113–127 West Eighteenth Street, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF DONALD H. POWERS, PH. D., RESEARCH DIRECTOR OF RICHARD HUDNUT, NEW YORK, N. Y.

Mr. KLEINFELD. Dr. Powers, you are research director for the Richard Hudnut Co.?

Dr. POWERS. That is right.

Mr. KLEINFELD. Are you a medical doctor?

Dr. POWERS. No; a Ph. D.

Mr. KLEINFELD. In what field?

Dr. POWERS. In chemistry.

Mr. KLEINFELD. Will you please read your statement?

Dr. POWERS. Richard Hudnut is one of the larger manufacturers of cosmetics in this country. At this time we are selling close to 700 different and distinct products—see exhibit I——and in a year's time will sell close to 40,000,000 separate packages. The type of products which we manufacture and distribute may be broadly classified as follows: Creams, lotions, deodorants, face and body powders, fragrances, lipsticks and rouges, nail lacquers, permanent hair waving solutions, shampoos, and hair dressings and rinses.

More than 90 percent of these products have been on the market for 10 years or more and several items have enjoyed consumer acceptance for at least 60 years. With such a large number of products of this type the problem of maintaining uniformity and quality of production is a major one. We have set up at Richard Hudnut a product-control procedure which is applied to every product which we sell.

While it would be impractical to furnish a list of the 800-and-odd raw materials currently used, it can be stated that specifications are set up for each raw material and the methods for testing each item are carefully spelled out. We are attaching—see exhibit A—our regular specification sheets for 10 of such items and these are submitted as typical. The test methods used are those found in the U. S. Pharmacopoeia, National Formulary, Toilet Goods Association, and in a number of cases our own test methods. The deviations permitted in the purity, melting point, water content, and the like are carefully spelled out. Shipments are tagged with the red rejection ticket—see exhibit B—if they do not meet these specifications in any point, and are returned to the supplier. Analyses of the raw material are recorded on the production sheet. A production procedure is written up for each product and an independent control checks each production lot to see that the procedure is followed. The lot number on analysis of each raw material going into the batch is recorded on the batch record. When

each batch is manufactured it is submitted to control for analysis to check its purity and quality before it is bottled or packaged. After packaging it is again analyzed—see exhibit C—to insure product uniformity in the final package. Control maintains inspectors to see that packages are properly labeled, filled, and sealed. Records are kept of each lot and the ingredients going into it and their analyses and samples of each bath are kept. Each package is coded to tell when it was manufactured and packaged and the lot number. This control procedure is set up to maintain the uniformity of the product once it is put on the market and as indicated above it takes care of the majority of our products.

However, when a new item is put on the market, tests prior to marketing fall into two categories: One, tests on a product which is essentially the same as a product now on the market and, two, tests on products which are new or which contain chemicals which are of unknown or uncertain irritation or sensitivity.

In discussing the use of chemicals in the cosmetic industry it should be borne in mind that in recent years purification and separation of the chemical compounds occurring in natural products have gone on as well as the synthesis of the same chemicals from "coal, air, and water." The natural fats and oils originally used were an indefinite mixture of as many as a dozen chemicals or 30 different chemicals. We have found that usually a few of these chemicals were of value while others were of little value. As we know more accurately the exact composition of natural products we are able to select those chemicals which specifically contribute to the effect desired, such as cleansing or softening action. The distillation at very high vacuum of natural fats and oils has contributed tremendously to our knowledge and the availability of pure chemicals from natural sources. If we truly know the purity of a product and all of its components it does not matter whether the chemicals used are from natural or synthetic sources.

In preparing new products of the first category for the market, it must first be established as a stable product which we can manufacture readily and uniformly. It is then paneled to a widely selected group of people along with a careful questionnaire. These questionnaires are collected and reviewed before a decision is made to market the product. Repeat sampling is also studied to further check on repeated use. These tests require from 2 to 3 months.

In the case of products in the second category, patch tests, irritation tests, and sensitization tests are run on rabbits before the panel tests are started on a widely selected group of people. The average time for testing and paneling runs for 6 months. Our own institute gives us a further chance to study new products under the application and observation of an expert. However, home-use panel testing gives a clearer picture of the variables and misuse that may occur in home use. Patch testing on 50 animals followed by panel testing on at least 200 people is indicated where a product is of uncertain or untested nature. A supplier of new chemicals should submit, and does submit, data on the toxicity, irritation, and sensitivity of any product going into the cosmetic industry, but the cosmetic manufacturer himself must control the uniformity of his product and determine the effect or possible irritation of the new chemical in the particular formulation or combination which he is distributing.

Specific examples showing the tests conducted on a product before putting it on the market are listed: Tru-Tint para hair dyes, home permanent waving solution, enriched creme shampoo, nail lacquer, children's home permanent, dandruff lotion—Hudnut.

And we picked these from widely selected groups to get a clear and accurate picture.

True-Tint para hair dyes:

(*a*) Bought a company selling para dyes with years of experience selling to leading salons throughout the country.

(*b*) Check irritation and toxicity on rabbits' skin and eyes.

(*c*) Run 350 tests on women in hair institute, patch testing each one and running repeat tests on 50 percent of them with many getting up to five and six para-dye applications.

(*d*) Careful control on raw materials and production.

(*e*) Test marketing in a limited area with careful check on complaints.

This product is still on market test and there is no irritation complaint on the first 100,000 units.

Hudnut home permanent:

(*a*) Chemicals tests on animals at medical school.

(*b*) Patch tested for irritation and sensitivity, under supervision of dermatologist.

(*c*) A medical study showed the absence of absorption of any ingredients through the skin.

(*d*) Institute tests for a year by skilled operators.

(*e*) Control on raw materials and productions.

(*f*) Distribution on limited basis with careful check of complaints.

(*g*) Received approval from cosmetic committee of American Medical Association, Good Housekeeping magazine, and Parents magazine.

Enriched creme shampoo:

(*a*) Review of published literature and data relating to soaps and shampoos.

(*b*) Animal tests for irritation and sensitivity.

(*c*) Institute tests for a year's time under supervised control.

(*d*) Control on raw materials and production.

(*e*) Initial sales in limited area.

Nail lacquer:

(*a*) Patch tests on 250 people by dermatologist.

(*b*) Panel tested.

(*c*) Quality-control set-up.

Then I would like to correct and say, submitted to the Cosmetic Committee of the American Medical Association and received approval. We originally received approval as hypoallergenic, and then decided to leave out the nonallergenic as not clarifying the picture. It has also been approved by Good Housekeeping.

Children's home permanent:

(*a*) Institute tests for 1 year's time.

(*b*) Hair tested for damage with new micro sound-wave technique.

(*c*) Control of raw materials and production.

(*d*) Test market in two cities.

(*e*) Full-scale marketing.

(*f*) Complaints less than 1 in 5,000 with 1 reported case of allergy in 1,000,000 units.

I should add to this one—approval by the cosmetic committee of the American Medical Society.

Dandruff lotion:

(*a*) Review literature and technical data from suppliers on all products involved.

(*b*) Animal tests for irritation and sensitivity.

(*c*) Institute testing for 6 months.

(*d*) Panel testing.

(*e*) Control and product standardization.

(*f*) Gradual marketing.

It should be be realized that 90 to 95 percent of the domestic products on the market are well established—time-proven formulations with years of consumer experience. Many of the new products coming on the market are slight modifications of these proven formulations. However, new products and products containing truly new chemicals are coming on the market. The chemical manufacturer should supply full data regarding the composition, safety, and toxicity of these products and the cosmetic manufacturer must check his final formulations. It is suggested that closer cooperation between the chemical manufacturer and cosmetic manufacturer will insure a better understanding of the limits of safety of any new formulation. We can never produce an absolutely safe product for all conceivable types of usage, and accurate analyses can only be made when the entire range of usage and consumer applications are known. The registration of every new drug with the Food and Drug Administration has not prevented the occasional human error or occurrence of product failure or toxicity in an unexpected phase of its use and application (e. g., bismuth suppositories and pyridine sedatives). The risk of damage from the use of new chemicals used in cosmetic application for external use only is, of course, far less than with products for internal use since extremely small amounts of chemicals are absorbed through the skin under any condition.

While the relative danger from the use of new chemicals in cosmetic products is far less than in food and drug products, this does not mean that careful premarketing testing must not be maintained. The manufacturers are supplying an increasing amount of data regarding the criteria of safety of their new chemicals and the cosmetic manufacturer must patch-test and panel-test and set up a careful series of control tests before putting a new product on the market. It is doubtful whether the registration of cosmetics under the new drug rulings would have anticipated or avoided the cases frequently cited of harmful shampoos, waving lotions, and nail lacquers. New legislation to enforce pretesting and registration of every new cosmetic product woud put a terrific load on its administration and require a great many decisions regarding all the foreseeable circumstances under which each product should be tested. The present care used in the development of new cosmetics and the extreme rareness of serious consumer damage by new cosmetics further suggest no immediate crisis demanding controls and restrictions. Enough freedom must be left so that new products will be developed and marketed, or progress in the industry will be stifled.

Finally, it is felt that the industry does recognize its own responsibility to its customers and will and must steadily increase its pretesting and product evaluation before marketing.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Powers, on page 4 of your statement, in discussing the nail lacquer, you say that the product was submitted to the Cosmetic Committee of the American Medical Association.

Dr. POWERS. That is right.

Mr. KLEINFELD. And received approval as a nonallergenic nail lacquer; is that correct?

Dr. POWERS. It received approval as hypoallergenic. I wanted to correct that. That was incorrect in my statement. It was changed. I would like to correct it to say "received approval" period. Cross out that line.

Mr. KLEINFELD. Do you submit all of your products to the Cosmetics Committee of the American Medical Association?

Dr. POWERS. We do not.

Mr. KLEINFELD. Why did you submit just that one and no others?

Dr. POWERS. We submitted the home-permanent-waving lotion, we submitted the children's home permanent, we submitted a number of others. We regularly submit them to the cosmetics committee.

Mr. KLEINFELD. Why do you submit some and not all?

Dr. POWERS. I don't know.

Mr. KLEINFELD. You say on the last page of your statement, Doctor, that—

> It is doubtful whether the registration of cosmetics under the new drug rulings would have anticipated or avoided the cases frequently cited of harmful shampoos, waving lotions, and nail lacquers.

Is that correct?

Dr. POWERS. That is right.

Mr. KLEINFELD. Do you put out shampoos?

Dr. POWERS. That is right.

Mr. KLEINFELD. What tests do you make before you put out your shampoos?

Dr. POWERS. We would today run eye tests. On the other hand, I think the testimony of Dr. Sulzberger yesterday morning clearly pointed out that anyone reasonably careful in the field of shampoos would not have considered an eye test necessary prior to 3 months ago.

Mr. KLEINFELD. Do you shampoo your hair?

Dr. POWERS. Regularly.

Mr. KLEINFELD. You never got any shampoo in your eyes?

Dr. POWERS. Yes, I have.

Mr. KLEINFELD. Then do you have to be a soothsayer to believe that some damage might occur to your eyes?

Dr. POWERS. I think all shampoos are irritating to the eye.

Mr. KLEINFELD. It is a question of degree?

Dr. POWERS. That is right.

Mr. KLEINFELD. Do you make shampoos for children?

Dr. POWERS. Not specifically designated.

Mr. KLEINFELD. Children's hair is shampooed from time to time, is it not?

Dr. POWERS. Sure.

Mr. KLEINFELD. Did you ever see a child's hair being shampooed?

Dr. POWERS. Yes.

Mr. KLEINFELD. Did you ever see shampoo get in the kid's eyes?

Dr. POWERS. Yes.

Mr. KLEINFELD. Then wouldn't a careful manufacturer want to see to it that his product would not cause any damage to someone's eye?

Dr. POWERS. Yes.

Mr. KLEINFELD. And now you do make such tests, don't you?

Dr. POWERS. The point you ask—in the field of shampoo manufacture I am sure that all the manufacturers are very careful to see that the product is not harmful. As Dr. Sulzberger so carefully pointed out yesterday morning, prior to 3 months ago we all recognized that shampoos cause eye irritation. We all recognized that there was a possibility of shampoos getting in the eye. On the other hand, I have seen no evidence to indicate there were any new products on the market that were more irritating or more damaging than shampoos that have been on the market for 150 years.

That doesn't mean as of today, in the light of the new evidence, that every manufacturer—I think every manufacturer would check shampoos for eye irritation. It is because we hadn't realized the possible damage of excessive quantities of shampoos getting in the eye.

Mr. KLEINFELD. You hadn't recognized it?

Dr. POWERS. And in our own experience in selling millions of shampoos we have had no case of that brought to our attention.

Mr. KLEINFELD. But finally it happened?

Dr. POWERS. We have had no case of it.

Mr. KLEINFELD. It happened with shampoos.

Dr. POWERS. So I understand.

Mr. KLEINFELD. How would existing law have avoided such injury?

Dr. POWERS. I suggest if this question of shampoo had come up a year ago, existing law or the present drug law would not have avoided it, because it would have been approved as an adequate, satisfactory shampoo.

Mr. KLEINFELD. Approved by whom?

Dr. POWERS. By the FDA as a drug. If it had been controlled under the so-called new drug law, the shampoo would have been approved on the basis of our knowledge at that time. On the basis of our knowledge today we wouldn't put out any shampoo——

Mr. KLEINFELD. Do you know that as early as 1944, Doctor, the Food and Drug Administration published information to the effect that if any product might get into mucous membranes it should be tested in the eyes of a rabbit?

Dr. POWERS. Yes.

Mr. KLEINFELD. Wasn't that a sufficient warning?

Dr. POWERS. Shampoos are tested in eyes of rabbits and they give irritation. Soap gives irritation to the eye of a rabbit today.

Mr. KLEINFELD. Wait a minute, Doctor. These two shampoo preparations which were seized caused fairly serious eye injury.

Dr. POWERS. I have seen no evidence of any permanent injury.

Mr. KLEINFELD. Let's assume that they did. We have been advised they did serious damage. If——

Dr. POWERS. But——

Mr. KLEINFELD. Just a minute. Let me ask a question and then you can talk all you want.

If that is a fact, and if it is a fact that putting a few drops of this shampoo into a rabbit's eye would have caused serious similar injury to the eyes of a rabbit, if that had been done, wouldn't that have prevented the injury to the human being which resulted?

Dr. POWERS. Yes.

Mr. KLEINFELD. And now you perform such tests before you put out your shampoos?

Dr. POWERS. Any new shampoo would be tested, even an old formulation would be tested for the eye test. Because the experience, not of this committee, but the experience of the public at large have suddenly realized and brought up the point that the possibility of shampoo damage to the eye is something that had not occurred to us who have sold millions of bottles of shampoo with no complaint over a number of years' time. Today, because of such a possibility, we would check and recheck all our old formulations and new formulations in the eye. But a law would not have anticipated that, and I think the leading dermatologists would indicate that they would not have anticipated it.

Mr. KLEINFELD. And you think it would have been unreasonable to assume that a manufacturer of a shampoo would anticipate that his product might get into somebody's eyes and cause injury?

Dr. POWERS. He would expect it to.

Mr. KLEINFELD. If he would expect it to, would you not think he would make tests beforehand and find out if any injury were caused?

Dr. POWERS. He would expect it to be very promptly washed out, as it usually is.

Mr. KLEINFELD. In what way?

Dr. POWERS. With water. It usually is.

Mr. KLEINFELD. If he would expect it, would he find out by testing it?

Dr. POWERS. The point I want to make clear is that any shampoo tested in the eye would show irritation, and if washed out, it will clear up.

Mr. KLEINFELD. And if it caused more serious irritation and injury, then what?

Dr. POWERS. I know of no case of a shampoo causing blindness.

Mr. KLEINFELD. I didn't say caused blindness, I said serious eye injury.

Dr. POWERS. I know of no such case.

Mr. KLEINFELD. Do you think such injury is inconceivable?

Dr. POWERS. I am sure it is conceivable.

Mr. KLEINFELD. If it is conceivable, should not the careful manufacturer make proper tests beforehand?

Dr. POWERS. That is right. We certainly shall in the light of the possibility.

Mr. KLEINFELD. You say on the last page of your statement:

> New legislation to enforce pretesting and registration of every new cosmetic product would put a terrific load on its administration and require a great many decisions regarding all the foreseeable circumstances under which each product should be tested.

Do you know that the drug industry has to make such tests?

Dr. POWERS. That is right.

Mr. KLEINFELD. And you know that there is testimony before this committee that since 1939 when this law went into effect approximately 7,500 new drug applications have been filed?

Dr. POWERS. That is right.

Mr. KLEINFELD. And of these 7,500 approximately 5,000 have been approved by the Food and Drug Administration; that of the remaining 2,500 less than a score were formally rejected. Most of the 2,500, this committee was told, were voluntarily withdrawn by the manufacturer after a determination was made by the Food and Drug Administration that the evidence of safety was insufficient.

There was testimony also that only about eight of these applications were appealed to the Federal Security Administrator from the decision of the Food and Drug Administration, and only one was made a subject of court action. Does that indicate that the drug industry has been suffering grievously because of the new drug section?

Dr. POWERS. No, it does not.

Mr. KLEINFELD. Do you know what caused the new drug section to be put into the law?

Dr. POWERS. No.

Mr. KLEINFELD. It was finally put into the law because an untested drug was put out which killed a hundred people. You wouldn't want to recommend that we wait until serious injury occurred, would you?

Dr. POWERS. No, indeed.

Mr. KLEINFELD. Now, the patch testing which you discussed is rather important, is it not?

Dr. POWERS. Well, there are two types of patch testing: There is the exploratory patch testing and the routine patch testing.

Mr. KLEINFELD. Yes?

Dr. POWERS. Exploratory patch testing should be and must be under a doctor, dermatologist. Routine patch testing, of course, is indicated in the Food and Drug law at the present time for hair dye, and I think in the case of routine patch-testing experience over the past years it has shown that routine patch testing of a product that has been exploratory patch-tested and is established for irritation or lack of irritation, that routine patch testing does not necessarily have to be under a dermatologist, although that must be essential under exploratory patch testing.

Mr. KLEINFELD. Before you put out a product you do perform exploratory patch testing?

Dr. POWERS. We do, indeed.

Mr. KLEINFELD. Under whose supervision?

Dr. POWERS. A dermatologist.

Mr. KLEINFELD. Would you feel safe in going along for years and putting out your product without exploratory patch testing under the general supervision of a dermatologist?

Dr. POWERS. No, I would not.

Mr. KLEINFELD. Have you received some valuable information from the patch testing?

Dr. POWERS. Yes, indeed.

Mr. KLEINFELD. And that is followed by use tests?

Dr. POWERS. That is right.

Mr. KLEINFELD. And if that type of patch testing is not performed and supervised by a dermatologist, and use testing is not employed under the general supervision of a dermatologist, it is quite possible injury may result; is that correct?

Dr. POWERS. That is possible.

Mr. KLEINFELD. So those things should be done by careful cosmetic manufacturers before they put their products on the market?

Dr. POWERS. That is right.

Mr. KLEINFELD. And if he doesn't, he is taking the chance it may injure somebody?

Dr. POWERS. That is right.

Mr. KLEINFELD. They all ought to do it?

Dr. POWERS. That is right.

Mr. KLEINFELD. I have nothing further.

The CHAIRMAN. No further questions.

Mr. HORAN. I want to say that is a very good statement, and the examples you supplied us were very interesting.

Dr. POWERS. Thank you very much.

(The exhibits submitted by Dr. Powers are in the files of the committee.)

Mr. KLEINFELD. Is Dr. Russell here?

Dr. RUSSELL. Yes.

The CHAIRMAN. Your name and address?

Dr. RUSSELL. Kenneth L. Russell, 105 Hudson Street, Jersey City, N. J.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF KENNETH L. RUSSELL, PH. D., CHEMIST, COLGATE-PALMOLIVE-PEET CO., JERSY CITY, N. J.

Mr. KLEINFELD. Will you read your statement, Dr. Russell.

Dr. RUSSELL. I am Kenneth L. Russell. I am assistant research director of Colgate-Palmolive-Peet Co. I have a Ph. D. degree in chemistry from New York University. I have been employed for 16 years in the research and development department of said company where my work has consisted of research on synthetic detergents and on cosmetics and toilet articles. For over 10 years my work has dealt almost entirely with cosmetics and toilet articles, mainly supervising the work of other chemists on these products.

The Colgate-Palmolive-Peet Co. manufactures and sells shampoos, hand lotions, face creams, face powders, dental creams, tooth powders, denture cleansers, brilliantines, lipstick, deodorants, shaving creams, bubble-bath preparations, talc powders, after-shave lotions and many other products.

It would be impossible in the interval of time suggested by the committee to prepare a complete description of all of the cosmetics and toilet articles of the Colgate-Palmolive-Peet Co. and the tests conducted on all of them prior to marketing. We plan to present here a general description of the types of studies which are made on our products before marketing them and then give formula ingredients and other specific information on a few products introduced during the past several years to illustrate the general procedure.

Our research and development department is charged with the responsibility of developing new products and processes and improving existing ones. This department has about 200 technically trained chemists and chemical engineers aided by about an equal number of nontechnical people. It is difficult to state accurately the number of

persons connected with cosmetic and toilet articles research for this varies from time to time, but an average would be about one-fourth of the personnel.

The idea for a new product or product improvement may come from other departments of the company, such as the sales and advertising departments. They may recognize a consumer desire for a product having certain properties not appearing in existing products and request work to develop one having these properties.

Development of a new product starts in the laboratory. One part of the laboratory work consists of evaluating new products and raw materials that appear on the market. Performance tests are developed to help evaluate such products and raw materials, and often the idea for a new product will arise from such evaluation work.

A duty of our research personnel is to keep up with the scientific literature. Study of this literature may give rise to the idea that a new raw material or combination of materials might yield an improved product.

When the idea has been discussed and approved by management the project is set up and laboratory work starts. The steps in laboratory formulation and later pilot plant development to obtain a product having desirable physical properties are long and often discouraging but these are not of interest to this committee. Likewise the extensive work that is done to establish that the product is effective in performing in the intended manner is an interesting story, but not a part of this statement. We shall describe instead the steps involved in assuring ourselves that the product is safe for public use.

The safety of a product depends first on the raw materials entering into it, and for this reason a careful study is made of all raw materials which we use. It is part of our technical people's job to learn all they can about the raw materials they use in their formulation work. This information may be obtained from the literature, or from data furnished by the suppliers of the material. When these data are insufficient to establish that the material is a safe one for the intended use, we have tests conducted to obtain the necessary information. When in doubt concerning the best testing program to set up we have found that the Pharmacology Division of the Food and Drug Administration have been helpful in giving advice on this. Such tests usually consist of one or more of the following types of tests, depending on the amount of reliable information available from the other sources:

Toxicity tests on one or more species of animals: Acute toxicity, chronic toxicity.
Irritation tests on rabbit skin.
Irritation tests on rabbit eyes.
Human patch tests.
Human usage tests.

The above tests are conducted by dependable outside consulting laboratories who not only run the tests for us, but give us in addition the factual results and unbiased interpretation of these results with respect to the safety of the material. Our eventual use of the material is decided upon only after this information is available and considered carefully by our own technical staff.

In addition to our regular employees our research and development department has consulting arrangements with many experts in various

fields. These men, too, often advise on the testing program to be set up to determine the safety of a material and help in the evaluation of the results of the program.

After a raw material has been proved safe to use it is part of our men's responsibility to see that it is always obtained in uniform quality. Tests must often be developed which will be used to determine the purity and characterize the material so that high quality material will always be used. After the material is in use each shipment is tested by our control laboratories to see that it meets the quality requirements set for it. This testing of raw materials is considered a very important part of our control of the quality of our cosmetic products, for it is often difficult to make as meaningful tests on finished products which consist of mixtures of many materials.

We have discussed now the importance of a thorough knowledge of the raw materials entering into a product. It is also recognized that sometimes a mixture of raw materials will behave differently from any one of the materials making up the mixture. Therefore, when there is information that the material under consideration is likely to be a safe one we plan our toxicity and irritation testing program on a finished product, using a formula for the testing program identical with or very similar to what we think the final formula will be. At the start of the program we may not know well enough what the final formula will be and at the end of the program find that it is necessary to repeat some or all of the work. The questions of when to test, what to test, and how to test are ones requiring judgment, and we must depend upon the experience of our own personnel, outside laboratories, and expert consultants, plus the considered judgment of other departments in our management to answer these questions.

After we have sufficient evidence that a product is safe for human use, before we sell the product we always obtain some consumer usage information from our own chemists and management using the product, and then further information which is furnished by the company's market research department. This department runs what are called blind product tests on experimental products. In these tests the product is packaged in coded containers and distributed to a panel of individuals across the country for trial and expression of opinion. Usually the product is tested in this way against a competitive product from the market or against one of our own regular products also packaged in a coded container. The individuals comprising the panel are sent the two samples along with a questionnaire asking for their preference on many points. They are also questioned concerning their reasons for liking and disliking each product. This information is of value in obtaining the most desirable physical and esthetic properties, but in addition we find it of value in indicating whether any unexpected or unusual physiological reactions result from use of the experimental product by these comparatively small groups of people.

After a product has gone through the consumer blind product testing program with no adverse results, it may then be decided to place it on public sale. In most cases first sale is limited to a few cities for a period of several months and expanded to the national market only after it has been shown satisfactory in the smaller market. This procedure, called sales testing, is partly to determine the sale potential of the product, but is also planned to determine whether any unforeseen

reactions develop from the use of the product. In most cases the names of purchasers are obtained during the sales test period, and personal interviews are conducted with a number of the purchasers, getting them to rate the product in comparison with other similar products they have used. Any adverse comments concerning our product are particularly noted and reported to management by the market research department. This report is given important weight when decision is made whether or not to expand the distribution of the product.

During the sales test period the production of the product is carefully followed to determine the best production and control procedures for later expanded operation. Also the product is often picked up from the stores in the sales test cities and returned to our laboratories for examination to see that it is holding up as expected under the varied conditions met in the field.

Having gone through the sales testing period with favorable results, decision may be made to sell the product on a national basis. During this period also, it is the responsibility of our technical people to constantly watch and control the quality of the product which is shipped from our factories. In the case of a new product special quality control measures are taken by a separate quality control division of the research and development department which may be decreased after a year or so, but constant effort is made to see that the products we sell and the raw materials entering into them are of standard quality.

It should be made clear that all of the steps which have been described above are not always taken before introduction of a new product or change in an existing product. The steps which are taken depend upon the experienced judgment of our own technical personnel and outside experts, based upon what is known from all sources which might bear upon the contemplated move, and what is unknown. We as a company have a business and a reputation to maintain. We cannot afford to make mistakes which might bring about serious loss of position in the industry.

As stated earlier, we will now give specific information on a few of our products and what studies were made before introducing them for sale.

Halo shampoo: This product consists of the ammonium salts of sulfated coconut oil monoglycerides, water, ethyl alcohol, and perfume. The ammonium salts of the sulfated monoglycerides are the active ingredients responsible for the foaming and cleansing action of the shampoo. They are manufactured by the reaction of glycerine and a sulfating agent with coconut oil, followed by conversion of the monoglyceride sulfates to ammonium salts. Since this active ingredient had not been used in cosmetics or toilet articles prior to the introduction of Halo shampoo, it was studied extensively before the product was placed on sale to the public. These studies consisted of determining the irritation of solutions of the material on the shaved skin of rabbits and in rabbits' eyes. Studies were made on the skin degreasing action of the solution by applying measured amounts of vegetable oil to rabbits and then washing it from their fur, followed by determination of the oil remaining in the hair and skin after excision, and histological examination of the skin, hair follicles, and sebaceous glands. In all of these studies, the solutions were compared with a mild soap shampoo and with a synthetic detergent shampoo

which was on the market. The skin and eye irritation were found to be less than for the soap shampoo. The rabbit-shampooing experiment indicated that the solution had excellent detergent properties with little effect on the natural oils and fats contained in the skin proper.

Acute toxicity studies were made on rats, guinea pigs, and dogs by feeding solutions of the material in various amounts to these animals, followed by histological examination of their organs after sacrificing those on lower dosages for 10 days. It was concluded that the material was innocuous, its toxicity being of an order that it was highly improbable that a sufficient amount could be ingested by a human at one time, even accidentally, to produce more than a mild gastritis and discomfort.

Reports of the extremely low irritation and toxicity properties of this product became available to us in 1937. In those days the human patch test was not well recognized as a technique for prediction of irritation, and our decision concerning the safety of the product for human use was based on the above careful animal studies. We distributed samples to a few employees for trial, and then to larger groups throughout the country. Results of these trials confirmed that the product was exceptionally mild.

In the fall of 1937 sale of the product was started, limited to the Cleveland district. After a few months in this market the distribution was expanded to the Chicago district, and in January 1939 to the entire country. Nation-wide experience has also confirmed that the products is extremely nonirritating and nontoxic.

Although the limited sale of the product was started on the basis of acute toxicity data, chronic toxicity tests were run on the material before national distribution. These consisted of feeding lower amounts of the solution to rats, guinea pigs, and dogs, sacrificing some of them at 30, 60, 90, and 180 days for histological examination. The results confirmed the safety of the product and showed that no permanent injury could result from its use, even under any conceivable misuse.

Veto deodorant cream: This product reduces the rate of flow of perspiration and because of this physiological effect is classified as a drug by the food, drug, and cosmetic laws. The product as introduced for national sale consisted of the following ingredients.

(The list of ingredients referred to is in the files of the committee.)

Dr. RUSSELL. Our laboratory work to develop a desirable product of this type extended over a period of several years. During this time we had discussions and correspondence with the Food and Drug Administration concerning contemplated formulations. We were requested to submit data on the suitability of the above emulsifying agent for use on the skin. Animal toxicity and irritation data which will be discussed more fully below under dental cream was submitted, and we were advised that a formula containing this agent, aluminum sulfate and other common creaming ingredients, would not be considered a new drug as defined in the law. Aluminum phosphate was included in the formula specifically to reduce corrosion of fabrics with which the product would come into contact during use. We were advised to cite as active ingredients on the label the aluminum phosphat and the aluminum sulfate. Results of product irritation and sensitization tests by the human patch-test technique were also sub-

mitted by us and discussed with the Food and Drug Administration, and likewise results of effects of the product on color and tensile strength of fabrics, and package copy and claims.

In the development of the product samples of experimental formulations, either the same as the finally adopted formula or minor modifications thereof, were sent out on blind product tests to about 11,000 individuals who used the products for several weeks. Reports from these tests did not indicate any unusual degree of skin irritation or other adverse responses.

When the product was introduced for sale in 1945 the distribution was limited to six sales-test cities for a period of about a year. During this period a check was made among actual purchasers of the product and their reactions to the product were obtained. No unexpected or unusual reactions were encountered and distribution was expanded Nation-wide.

While this product was on Nation-wide sale, our research continued on antiperspirants and it was found that a new antiperspirant agent was more effective than aluminum sulfate. This agent, aluminum sulfamate, had never before been used in deodorant creams. Since our work indicated it would be a valuable material for such use, we asked advice from the Food and Drug Administration on what program of testing we might set up in order to determine whether it would be safe. They suggested animal irritation and toxicity tests and human irritation and sensitization tests. This program was carried out, and results were favorable. A new drug application, giving details of these tests and results, was then filed with the Food and Drug Administration which was approved by them in November 1948. The new formula was as follows:

(The formula is contained in the files of the committee.)

Dr. RUSSELL. Before sale of the product, blind-product testing was conducted among about 3,800 individuals. Results of these tests revealed no unexpected or unusual reactions. Tests on fabrics (effect on color and tensile strength) also gave good results.

The product was placed on sale in the spring of 1949 in four sales-test cities and limited to these cities for about 1 year. Again consumers who had purchased the product were interviewed and their reactions obtained. No indications of unusual responses were evident and distribution was made national.

Ribbon dental cream: The company changed completely the formula for this product on a national basis in July 1942. The change was from a soap-chalk formula which had been sold for many years to a synthetic detergent-dicalcium phosphate formula. The new formula, which is also substantially the same as the present one, contained the following ingredients:

(The formula is contained in the files of the committee.)

Dr. RUSSELL. With the exception of the detergent, all of the materials were well known and established as safe for use in the mouth. In fact, all of them except the detergent had been taken internally in reasonable amounts by humans. Here then, it was necessary to establish the safety of the detergent for use in the mouth under conditions of normal dentifrice use and misuse.

Prior to the introduction of the new dental cream the detergent was studied very completely for toxicity, and also, of course, for irritating properties. Acute and chronic toxicity studies of 10 days and 180

days, respectively, were made on the detergent by feeding experiments on rats, guinea pigs, and dogs, followed by histological examination of the vital organs. As with the ammonium-salt detergent used in Halo, the sodium-salt was found to be of such a low order of toxicity that it was improbable that a human could ingest enough, even accidentally, to produce more than a mild disturbance. Irritation tests were run using solutions of the detergent of various concentrations on rabbits and in rabbits' eyes. As with the ammonium-salt detergent, the sodium salts were very mild in their action, both on the skin and in the eyes.

In order to develop a dental cream having desirable taste, foaming properties, color, consistency, et cetera, several different formulations were sent out to consumer panels in blind-product tests before the final formula was introduced for sale to the public. These formulas were small variations of the final formula, the composition of which is shown above. In these tests about 7,000 samples were distributed to individuals for usage for several weeks after which they reported their likes and dislikes by means of a questionnaire furnished to them. There were no indications of irritation from these usage tests.

Another factor of importance in connection with dentifrices is the abrasiveness of the composition. This was studied thoroughly in our own laboratories and dicalcium phosphate was found to be extremely nonabrasive to tooth enamel before the material was chosen as the polishing agent to be used in our formulations. By itself and combined with the other ingredients in the formula the material was found to be nonabrasive.

Sale of the product was started in the fall of 1940, limited to sale in four cities. It was sold in these cities for nearly 2 years before distribution was expanded to the national market. During this time there was no indication of any unusual irritation reactions. Experience in the sales-test cities and later sale on a Nation-wide basis confirmed the safety of the product.

In closing, may I point out that the present law forbids the sale of products which contain any substance which may render them injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual, and provides penalties for violations. The Food and Drug Administration has been vigilant to protect the public interest by enforcing the law and it has been my experience that they have also been most helpful to companies which seek their assistance. In addition, I believe most manufacturers realize that it is good business to market only products which the consumer finds satisfactory and therefore take all reasonable steps to assure the quality and safety of their products.

Mr. KLEINFELD. Dr. Russell, does your company make any soaps?

Dr. RUSSELL. Yes; we do.

Mr. KLEINFELD. They don't appear to be listed in the list which you gave us.

Dr. RUSSELL. Our understanding was that the committee was set up to study cosmetics and as soaps aren't defined as cosmetics——

Mr. KLEINFELD. Well, we asked you in our telegram to include soaps; did we not?

Dr. RUSSELL. Yes; we received a telegram asking us to include soaps and detergents, and we interpreted that to mean insofar as cosmetics were concerned. I have covered the synthetic detergents

rather thoroughly, and other of our cosmetic formulas which contain soaps.

Mr. KLEINFELD. Well, when we said soaps, we meant soaps, of course.

Do you make any soaps?

Dr. RUSSELL. Yes.

Mr. KLEINFELD. How many?

Dr. RUSSELL. I can't answer that. Very many.

Mr. KLEINFELD. Do you perform the same kind of testing on your soaps as with your other cosmetics?

Dr. RUSSELL. I am not very well qualified to answer that question because my field is all the toilet articles, and we do not consider soaps in the toilet articles division of our company.

Mr. KLEINFELD. Why is that?

Dr. RUSSELL. I can't answer that, except that is the way it has been set up by management.

Mr. KLEINFELD. Palmolive soap is your product?

Dr. RUSSELL. Yes, sir.

Mr. KLEINFELD. Would you not call that a toilet article?

Dr. RUSSELL. It is a toilet article, but not a cosmetic, as defined by the Food, Drug, and Cosmetic Act.

Mr. KLEINFELD. Well, not a cosmetic because the act excludes soaps in so many words?

Dr. RUSSELL. That is correct.

Mr. KLEINFELD. Why should soaps be excluded from the definition of cosmetics?

Dr. RUSSELL. Well, perhaps, because they are so well known. When we refer to soaps as salts of fatty acids, they were well known and used for many years without damaging effect.

Mr. KLEINFELD. Not all soaps are made of the same material; is that correct? Is your soap like all other soaps?

Dr. RUSSELL. As I said, I am not a soap man.

Mr. ABERNETHY. I would say they are better.

Mr. KLEINFELD. Maybe, but soaps are made of different ingredients; are they not?

Dr. RUSSELL. Soaps are made from the reaction of a fatty oil with caustic to produce the sodium salts of fatty acids, which are soaps.

Mr. KLEINFELD. Different formulas are used; are they not? Are perfumes added from time to time?

Dr. RUSSELL. Perfumes——

Mr. KLEINFELD. And other materials—coloring?

Dr. RUSSELL. I am not a soap expert. Perfume and coloring, yes.

Mr. KLEINFELD. If we assume that different materials are used in soaps, just as are different materials are used in cosmetics, is there any reason why the same precautions should not be taken with soaps as with other cosmetics?

Dr. RUSSELL. Not in my opinion; no, sir.

Mr. KLEINFELD. Soaps can get in your eyes as well as shampoos?

Dr. RUSSELL. Surely.

Mr. KLEINFELD. In fact, what is the difference between soap and a shampoo?

Dr. RUSSELL. I mentioned in here a soap shampoo and a synthetic detergent shampoo.

Mr. KLEINFELD. For instance, you might shampoo your hair with a regular bar of soap, if it were a good soap like Palmolive?

Dr. RUSSELL. Yes; I think there are advantages in using a special shampoo.

Mr. KLEINFELD. Are your products submitted to the Committee on Cosmetics of the American Medical Association?

Dr. RUSSELL. No, sir.

Mr. KLEINFELD. On page 3, Doctor, you discussed certain tests which were made, and one of the tests mentioned is irritation tests on rabbit eyes. You do that with your shampoos?

Dr. RUSSELL. We have them done by outside laboratories; yes, sir.

Mr. KLEINFELD. Have you always done it on your shampoos?

Dr. RUSSELL. This goes back to 1937. It was done on this shampoo back in 1937; yes, sir.

Mr. KLEINFELD. So, back in 1937 you did make tests on rabbit eyes?

Dr. RUSSELL. Yes, sir.

Mr. KLEINFELD. With a shampoo?

Dr. RUSSELL. Yes, sir.

Mr. KLEINFELD. You thought it was necessary?

Dr. RUSSELL. Yes, sir.

I must say in that connection, I am not sure they were rated in the same way they are rated now in those irritation tests, but they were compared with a soap solution and in this case found to be less irritating than soap solution under the same conditions of tests.

Mr. KLEINFELD. But the solution was put in the eyes of rabbits before it was sold on the commercial market?

Dr. RUSSELL. That is right.

Mr. KLEINFELD. I think you said we should do the best we can in making tests before putting any product on the market, and even though perhaps all injury cannot be avoided, possibly, you think everybody should do his best to minimize, as far as possible, any adverse reaction to the consumer; is that right?

Dr. RUSSELL. Yes.

Mr. KLEINFELD. And that would include patch tests?

Dr. RUSSELL. In most cases.

Mr. KLEINFELD. Well, when wouldn't you use patch tests?

Dr. RUSSELL. Well, it depends on the change in the product. Some of the other people have mentioned where you are changing proportions of the ingredients in a formula you might not, as where you are changing a shade of face powder.

Mr. KLEINFELD. If you change proportions, wouldn't that indicate to you that you should make a patch test?

Dr. RUSSELL. That would depend on how great the change in proportions was. The point I am trying to make is that I believe you must use judgment in these things.

Mr. KLEINFELD. Who in your company exercises that judgment?

Dr. RUSSELL. Our technical people, plus the consultants that I have mentioned. We have a consultant dermatologist who would help on that.

Mr. KLEINFELD. And do you seek his advice on each change in formula?

Dr. RUSSELL. No, we do not. Sometimes we use our own judgment.

Mr. KLEINFELD. Thank you, Doctor, I have no further questions.

The CHAIRMAN. Mr. McDonough.

Mr. McDONOUGH. Do you recall any instances where your products—or would it come to your attention where there was any complaint from the public about deleterious effects from using your products?

Dr. RUSSELL. No, sir; some letters I am sure we have had which sound like allergies.

Mr. McDONOUGH. I mean serious effects.

Dr. RUSSELL. No, sir.

Mr. McDONOUGH. Do you think there should be any additional legislation necessary to protect the public's health in the use of cosmetics?

Dr. RUSSELL. I think that is a very difficult question to answer, and it is a very difficult problem. I think the matter of definition is very difficult, the difference between a drug and a cosmetic, and when you would say a cosmetic it might be a drug. I think it would be a very difficult problem. I feel that the companies must protect the public, the public must be protected against possible things that can be done.

Mr. McDONOUGH. Do you use any estrogenic hormones in any of your products?

Dr. RUSSELL. No, sir; we do not.

Mr. McDONOUGH. Do you think there is a difference between the cosmetic effect of an application and the therapeutic effect of an application? In other words, do you think the cosmetic effects are therapeutic at all?

Dr. RUSSELL. Yes; in some cases. Certainly the antiperspirant is a therapeutic effect. It is a drug effect. It is a physiological effect.

Mr. McDONOUGH. Although the Food and Drug didn't agree and wouldn't put it on the drug list for you?

Dr. RUSSELL. They agreed it was a drug, but not a new drug. Then when we asked to use a different material, they said, "That is a new drug."

Mr. McDONOUGH. So it is a cosmetic, and you have to pay the luxury tax to buy it?

Dr. RUSSELL. No, I am not sure of the tax situation.

Mr. McDONOUGH. I mean if it is a cosmetic, you pay it, and if it is a drug, you don't?

Dr. RUSSELL. I don't know.

Mr. McDONOUGH. That is all.

The CHAIRMAN. Thank you, Doctor.

Mr. KLEINFELD. Mr. Martin.

The CHAIRMAN. Your name and address?

Mr. MARTIN. Jean Martin, Fifth Avenue—Rockefeller Center, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. Mr. Martin, I see it is so late, I wonder if you can come back on Monday?

Mr. MARTIN. Certainly.

The CHAIRMAN. We will call you on Monday as the first witness.

Mr. KLEINFELD. We have two doctors scheduled for Monday morning. If Mr. Martin comes at 11 o'clock, we can put him on then. Will that be all right?

Mr. MARTIN. Surely.

The CHAIRMAN. We will recess until Monday morning at 10 o'clock.

(At 4:45 p. m., a recess was taken until Monday, January 14, 1952, at 10 a. m.)

CHEMICALS IN FOODS AND COSMETICS

MONDAY, JANUARY 14, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS IN FOODS AND COSMETICS,
New York City, N. Y.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess.; continuing of the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 10 a. m., in room 128, United States Courthouse, New York City, N. Y., Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney of New York, Hedrick of West Virginia, and Horan of Washington.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. Let the committee be in order.

Call your first witness, Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Peck.

The CHAIRMAN. Your name and address, Doctor?

Dr. PECK. Samuel M. Peck, 33 East Seventieth Street, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF SAMUEL M. PECK, M. D., NEW YORK, N. Y.

Mr. KLEINFELD. Dr. Peck, where did you obtain your medical degree?

Dr. PECK. College of Physicians and Surgeons, Columbia University, 1924.

Mr. KLEINFELD. And you are a fellow of the American Medical Association?

Dr. PECK. I am a fellow of the American Medical Association.

Mr. KLEINFELD. How long have you specialized in the field of dermatology?

Dr. PECK. For over 20 years.

Mr. KLEINFELD. Are you certified in that specialty by the American Board of Dermatology and Syphilology?

Dr. PECK. I am.

Mr. KLEINFELD. Are you a member of the American Dermatological Association?

Dr. PECK. I am.

Mr. KLEINFELD. And a member of the American Academy of Dermatology and Syphilology?

Dr. PECK. I am.

Mr. KLEINFELD. And you are affiliated with the American Public Health Association?

Dr. PECK. I am. I am a fellow.

Mr. KLEINFELD. And you are a coauthor with Dr. Louis Schwartz of a book in the field of dermatology?

Dr. PECK. I am.

Mr. KLEINFELD. What is the name of the book?

Dr. PECK. Cosmetics and Dermatitis, and another book—Occupational Diseases of the Skin.

Mr. KLEINFELD. Also with Dr. Schwartz?

Dr. PECK. Also with Dr. Schwartz.

Mr. KLEINFELD. Have you contributed papers in the field of dermatology to the professional publications?

Dr. PECK. About a hundred.

Mr. KLEINFELD. Are you also a practicing dermatologist?

Dr. PECK. I am also a practicing dermatologist.

Mr. KLEINFELD. Do cosmetic producers, manufacturers, and distributors consult with you from time to time?

Dr. PECK. They do from time to time.

Mr. KLEINFELD. Will you please read your statement.

Dr. PECK. Most of the ill effects which I have encountered following the use of cosmetics have been in the form of a contact dermatitis. In the great majority of cases, the eruption was of an allergic nature. Contact dermatitis can be caused by both primary irritants and sensitizers.

Primary irritants and sensitizers can be defined as follows: A primary cutaneous irritant is an agent which will cause dermatitis by direct action on the normal skin at the site of contact if it is permitted to act in sufficient intensity or quantity for a sufficient length of time.

A cutaneous sensitizer is an agent which does not necessarily cause demonstrable cutaneous changes on the first contact, but may effect such specific changes in the skin that after 5 to 7 days or more, further contact on the same or other parts of the body will cause dermatitis. In other words, following the development of an allergic state.

A primary irritant may also be a sensitizer. In such an instance, the primary irritant is used in a dilute concentration so that it does not act as a primary irritant any longer, but only elicits a reaction in the skin when the sensitivity develops.

In the majority of the cases, only a few individuals develop dermatitis from sensitizers in cosmetics. Such chemicals are innocuous to most people. Allergic dermatitis in the average case is due to a peculiar constitutional idiosyncrasy in the allergic individual. There are chemicals, however, which have a high potential for causing sensitization reactions. Their use may effect such a large percentage of people that these chemicals should probably not be used in cosmetics.

A sensitization dermatitis unlike that due to most primary irritants only develops after a lapse of time which is referred to as the incubation period; that is the period of time during which sensitization takes place. Once this sensitivity develops, not only will the area where the cosmetic or the chemical was applied show a specific reaction, but sites which were never in contact with the chemical in the first place will also become sensitive. This is the point which I tried to bring out in the definition of a sensitizer. This statement is true of most allergic contact dermatitis.

This induced sensitivity or allergy is specific and in the average case will only be elicited by contact with a chemical of the same or closely related structure. It should also be pointed out that even with the specific allergic dermatitis those areas in the skin where abrasions are present or which have an unusually thin layer of epithelium are more easily sensitized than other normal areas of skin.

The incubation period for the development of sensitivity varies. It depends to some extent on the nature of the sensitizer, its concentration, the duration in which it is used, and individual factors. The average time for the development of the sensitivity may be said to be between 10 to 21 days. In some instances it may take much longer. It is this difference in time that it takes for sensitivity to occur which renders it difficult in some instances to properly evaluate the potential sensitizing index of a chemical.

The cosmetic manufacturer who has any competent advisers on his staff will rarely, if ever, use a primary irritant in his cosmetic formulas unless it is used for specific reasons. The fact that irritants are rarely, if ever, used in cosmetics is borne out by the fact that occupational dermatitis among employees in a factory manufacturing cosmetics is relatively low. If the ingredients could be classified as primary irritants or strong sensitizers, much more occupational dermatitis would be seen among such employees.

In the textbook by Dr. Schwartz and myself—Cosmetics and Dermatitis (Paul B. Hoeber, 1946)—we give a list of chemicals which can act both as primary irritants and sensitizers. It must be borne in mind that in the list of chemicals which may act as primary irritants the concentration of these chemicals which do act as such irritants is, as a rule, not used in most cosmetic formularies.

Certain cosmetic procedures, such as depilation, hair waving, and hair straightening employ chemicals which are known to be primary irritants if they are allowed to act on the skin for a sufficient length of time. In most instances, especially in the use of hair-waving preparations, it is the operators in the beauty parlors who suffer more from the dermatitis than the users. This is due to the fact that they come in contact with these irritants much more frequently and for a much longer duration of time than the users of such cosmetics.

There are a number of chemicals which may act as weak primary irritants. These weak primary irritants may take weeks or even months of prolonged contact to produce a dermatitis. The action of such chemicals must be known before they are put on the market.

One must clearly differentiate between accidents which may occur from the use or rather from the misuse of cosmetics and those which may occur when indavertently some unknown chemical substance is used in a cosmetic formulation. There are instances where the use of a depilatory may cause a direct primary irritant dermatitis. This may be due to the fact that they are used on the wrong part of the skin or they have been left on too long. Also, there are rare individuals who become easily irritated even when the cosmetic is used in the prescribed manner. Such facts must be recognized by both the manufacturer so that he can give proper instructions and point out the possible reactions which may occur after the use of such cosmetics, and by the users so that they can take the proper precautions by being informed properly of the possible dangers from the misuse of these cosmetics.

I am strongly in favor of a regulation that would require a manufacturer to properly acquaint himself with the dangers which might occur from the use of a new chemical whose potential toxicological or sensitizing potency is unknown. Enough time has elapsed in the use of the common ingredients which go into most cosmetic formulations so that one does not have to fear that there is not sufficient data to allow such chemicals or their combinations to be put on the market.

However, with the rapid strides which are being made in the chemical field and with the newer substances which are being introduced into both foods, drugs, and cosmetics, I believe that it is important that before such new chemicals are placed on the market that their properties should be investigated from every angle. It would be helpful both to the manufacturer as well as to the authorities who are responsible for the proper administration of any law for the regulations of such sales, if it was clearly stated just what testing is required by the manufacturer before such new chemical formulations come into general use.

The work that was done during the war, where many new types of chemicals were used in materials which come into close contact with the skin has brought out the value of the procedures recommended for evaluation of the irritating and sensitizing potentials of the new chemicals which were introduced at that time. It must also be pointed out that in rare instances the use of a known substance in an entirely new type of vehicle should, perhaps, be classified as a new drug and require retesting. This is so because the use of a vehicle which allows for more intimate contact of the chemical with the skin may facilitate absorption and may render the toxicological data and the previous sensitizing evaluation of the chemical incomplete under the new set of conditions.

Once it has been decided that no new chemicals can be used in cosmetics without proper testing, it would be insufficient just to write that into the law, unless as I said before, the proper procedure for testing was agreed upon. Such proper procedures are not easy to formulate and I can only state my opinion in a general way which I am sure will need precise modification after proper consultation and conference with authorities in the field. I would like to make the following suggestions.

1. Toxicological studies on animals including tests for primary irritation should be required.

2. Once the chemical or the formulation has been proven to be nontoxic in the manner in which it is to be used, the sensitizing index of the chemical or chemicals combined in the preparations should be determined. The minimum number of test persons should be 200. However, because of the possible factor of statistical error, 500 would probably be a better group to use. Usage tests under the supervision of competent authorities are by and large better than repeated patch tests especially where cosmetics are employed. In my opinion, a dermatologist who is an American Board member is best qualified to supervise the testing of such cosmetics. I say this not because I am a dermatologist, but because I have found that the particular training which a dermatologist has received allows him to recognize minor reactions and early reactions which would not be noted by those improperly trained. These minor reactions might later turn out to be important.

Finally, it must be emphasized again that unpredictable and unknown reactions from chemicals may occur which cannot be predetermined by any sort of testing. Such is best exemplified by the nail changes following the use of fingernail coatings. The important thing is that once such reactions occur, they should be recognized and properly evaluated.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Peck, you say on page 2 of the statement that we have that——

> The cosmetic manufacturer who has any competent advisers on his staff will rarely if ever use a primary irritant in his cosmetic formulas unless it is used for specific reasons.

What do you include in the term "competent advisers"?

Dr. PECK. A competent adviser would be properly covered by a number of men. One is a chemist who knows the possible changes which may occur in the chemical once it is put in a preparation under varying conditions. Then the final state of chemicals when they are formulated in the cosmetic.

No. 2. Competent medical or trained authorities who would be able to test out the toxicological properties of any of the chemicals.

Finally, as I tried to emphasize in my prepared statement, if it is to be used on the skin, I believe he should have a competent dermatologic authority to advise him on the sensitizing, irritating properties of the chemicals and their reaction as to the skin.

Mr. KLEINFELD. Then, as I gather your statement, you don't believe it would be nearly satisfactory if the cosmetic manufacturer merely employed a few chemists to make tests; is that correct?

Dr. PECK. That is correct.

Mr. KLEINFELD. Later on you make this statement, Dr. Peck:

> There are a number of chemicals which may act as weak primary irritants. These weak primary irritants may take weeks or even months of prolonged contact to produce a dermatitis. The reaction of such chemicals must be known before they are put on the market.

Suppose I propose to put out a cosmetic. In order to be completely safe, I decide I will take this new concoction and use some on myself and on a couple of friends. Because I apparently suffer no adverse reactions, and these few friends or relatives don't, I then put the cosmetic on the market. Is that sufficient testing?

Dr. PECK. That certainly is not.

Mr. KLEINFELD. In your statement, you say—

> One must clearly differentiate between accidents which may occur from the use or rather from the misuse of cosmetics, and those which may occur when inadvertently some unknown chemical substance is used in a cosmetic formulation.

When you say "inadvertently," Doctor, what do you mean?

Dr. PECK. Let's take this, for instance. I have had this occur on a few occasions. A woman will buy a depilatory, and it may state how this should be used on the arms and legs—and the manufacturer is perfectly honest—for a certain period of time, and then she uses it to remove eyebrow hair, and some of it runs into her eye and may cause damage to the eye. That is a misuse of cosmetics.

Now, inadvertently, if I may go on, counselor, inadvertently using cosmetics is what happened recently when a base coat was put out for nail preparation. As I understand it from the long drawn-out

controversy which followed among medical men, the manufacturer apparently had competent medical authority, dermatologists, who then went on to test in the usual manner following some of the conditions laid down by Dr. Schwartz and myself for testing chemicals.

Now there they had an entirely new set of conditions inadvertently used. They had a synthetic resin and they had a formaldehyde preparation. Nobody knew, as far as I could tell—when we first saw those cases they were even unrecognized—that if some of that substance got under the nail it acted in two ways: One, it was a sensitizer as far as the formaldehyde was concerned, and two, resin produced keratosis of the nail bed. Perhaps they could have gotten competent authority in the allergy field and among the dermatologists who were acquainted with such substances, and who were especially acquainted with phenol formaldehyde resins, who could tell them that they should not use that type of preparation on nails because of its sensitizing potency. I certainly wouldn't, because during the war, while I was in the Public Health Service, we experienced formaldehyde dermatitis in airplane manufacture where phenol-formaldehyde resins were used, and it is a product I wouldn't use in cosmetics if it could be avoided.

Be that as it may, they followed the usual procedure, and apparently on hundreds of people they found a low index of sensitization. But inadvertently they didn't know there was a weak primary irritant reaction which under the nail produced almost a wartlike growth of the nail bed, and that is where we were puzzled, because it took weeks and even months to develop on some people, and we very often got a negative patch test to the formaldehyde fraction. Therefore, it must have been something in the resin or combinations that acted as an irritant.

I also heard recently about a quaternary ammonium compound, for instance, that was used in a shampoo, which produced corneal opacity when it got into the eye. Apparently they tested that substance, in the routine way and the controversy now is whether the right concentration of the shampoo was used for testing or whether I would recommend that you should use the eye as a test object.

To answer that last, I would recommend, as I have, that eye tests can be carried out on animals. Certainly you wouldn't use a human subject. You could have picked up that type of reaction probably by using a rabbit's eye.

Mr. KLEINFELD. Let's discuss the two situations which you mentioned, in reverse order. You say you would have tested that shampoo in the eyes of a rabbit before using it?

Dr. PECK. I don't think so. I would now.

Mr. KLEINFELD. You would not have then?

Dr. PECK. No; because—let me qualify it this way. If it was a brand-new chemical that had never been used, I would have required it, since I knew nothing about that chemical, that before they turned it over to me, they would have to give me the proper toxicological data, and I might have included at that time a rabbit-eye test, but not in an ordinary shampoo. But that I wouldn't call an ordinary shampoo. That was a chemical I knew nothing about, so I might have required a rabbit-eye test.

Mr. KLEINFELD. Suppose we have a situation where we want to concoct a shampoo and want to use a wetting agent which in itself,

perhaps, has been shown in certain concentrations not to prove harmful. We also want to use a quaternary compound which in itself, in certain concentrations, hasn't been shown to be harmful. We want to put the two things together. Wouldn't the manufacturer of the shampoo, if he were careful and if he knew that shampoo sometimes gets in people's eyes, wouldn't he as a conservative, cautious person, say "Let's do some animal testing first"?

Dr. PECK. He certainly should.

Mr. KLEINFELD. And in the case of the base coats, is it asking too much of a manufacturer to attempt to perceive the things that should happen?

For example, if I wanted to distribute a cosmetic for use on the surface of a person's nails, would it be very unlikely to forsee that some of it might get underneath the nail and touch the skin?

Dr. PECK. Not at all. It does.

Mr. KLEINFELD. Well, then, we ought to consider those contingencies before we put a cosmetic on the market, shouldn't we?

Dr. PECK. I think so.

Mr. KLEINFELD. Later on, Doctor, in your statement, you say there are rare individuals who become easily irritated even when the cosmetic is used in the prescribed manner. Probably a very small minority of the people?

Dr. PECK. Yes.

Mr. KLEINFELD. And I assume that such facts must be recognized by both the manufacturers and users of these preparations. They must be recognized by the manufacturer so that he can give proper instructions and point out the possible reactions which may occur by reason of the use of such cosmetics, and by the users, so that they may take the proper precautions by being informed properly of the possible dangers from the misuse of these cosmetics.

As I understand you, Doctor, you say you know there are people who misuse cosmetics?

Dr. PECK. Yes.

Mr. KLEINFELD. And the cosmetic manufacturer knows that too?

Dr. PECK. Yes.

Mr. KLEINFELD. We have all sorts of human beings. And since the manufacturer knows there are some people who may misuse his product and therefore may possibly be injured, should he put some warning on his label?

Dr. PECK. Yes.

Mr. KLEINFELD. As to the possible adverse reactions which may occur from misuse; is that correct?

Dr. PECK. That is correct.

Mr. KLEINFELD. In other words, if he says "Use this twice a day," and if he knows if it is used 3 or 4 times a day it may create some harm, he may say "Warning or caution: Don't use more than twice a day."

Dr. PECK. That is right.

Mr. KLEINFELD. And if he recommends it for use on the hands and arms, and for use in only a certain quantity, and if he knows there may be some danger of misuse, you believe, as I understand your statement, that the user should be warned specifically against misuse?

Dr. PECK. And in enough detail so it is properly understood.

Mr. KLEINFELD. You specify the general types of tests which might be set forth?

Dr. PECK. I do.

Mr. KLEINFELD. In view of the great numbers of chemicals used, the great numbers of preparations, the great numbers of combinations, the great numbers of spots on the body where a cosmetic may be used, I imagine that those tests, in fairness to the manufacturers, would have to be somewhat flexible, would they not?

Dr. PECK. Very flexible.

Mr. KLEINFELD. They might vary depending on all the criteria which I mentioned.

Dr. PECK. Yes.

Mr. KLEINFELD. And merely listing certain tests would be just a general guide; is that right?

Dr. PECK. That is right.

Mr. KLEINFELD. And you do believe that before some new preparation or even a changed formula of an existing preparation is sold, the general types of testing which you suggest should be carried out?

Dr. PECK. I do.

Mr. KLEINFELD. The patch tests which you recommend in item two—who should perform those tests, Doctor?

Dr. PECK. Well, I believe that a dermatologist is best qualified to perform those tests.

Now I want to make one thing clear. I am quite well acquainted with regulations that require that before a paraphenylenediamine hair dye is used that the beauty parlor operator dabs a little bit behind the ear and waits as long as 72 hours, if they are conscientious, in some instances, to make sure that the user is not sensitive. That I think is a rather silly procedure, because, first of all, if we should admit that test is sufficient, you may have what is known as a delayed reaction which might take 5 days. Let us say it is rare. Is the operator competent to determine a 1-plus reaction? Is anyone who doesn't understand the reaction of patch tests competent to pick up the minor reactions which may mean that allergy is about to develop?

This is from a purely scientific viewpoint and talking about tests which have proven their value.

Now, I will admit, and I will qualify that statement, that by and large if it has been shown statistically that it is sufficient for the beauty parlor operator to dab a little bit of dye on the neck and that in, let us say, 99.9 percent of the cases, or 95 percent, that is sufficient, well, then, it is a practical test and it has proven its worth. And, of course, the dermatologist has a little warped viewpoint. I see the cases in my office that get into trouble, so that statistically I may have the wrong impression, not having data as far as the industry at large is concerned. But for the testing for the sensitizing index of a chemical, I certainly think it is the properly trained dermatologist who is the one to conduct the test.

Mr. KLEINFELD. What kind of cases have you come in contact with, Doctor?

Dr. PECK. From the hair dyes particularly?

Mr. KLEINFELD. That is right.

Dr. PECK. Well, I have had cases of people who were sensitive to paraphenylenediamine hair dyes all the way from the slight dermatitis around the forehead to quite a generalized dermatitis.

I have had cases that had to be hospitalized.

I must say that considering the number of people who use hair dyes or are exposed to hair dyes, it is a small number. And I have had people who didn't realize that once they were exposed to a hair dye and became sensitized, they might also develop dermatitis from fur dyes. I have had quite a few of those.

I have seen a great many cases among people in the fur industry who handle the paraphenylenediamine dyes.

I have seen people who develop brittleness of the hair from just the use of the dyeing procedure without a sensitivity. But I must say, considering the number of people who use it, that number is quite small.

Mr. KLEINFELD. And if you apply a product on one spot on the body, the reaction may sometimes develop in some entirely different area, may it not?

Dr. PECK. It may; yes.

Mr. KLEINFELD. That is all.

The CHAIRMAN. Doctor, suggestions have been made that we have informative labeling. Could you give us the benefit of your experience on that?

Dr. PECK. One of the greatest obstacles of the practicing dermatologist in determining what ingredient or ingredients are the cause of dermatitis is the fact that he doesn't get enough information from the label just what the ingredients are.

In many instances, unless he is acquainted with the formulation, that is true. And the second thing is, very often while he may find some manufacturers who are very cooperative and will send him the ingredients, many won't, and he can't obtain the ingredients to do his testing.

Most manufacturers will label the ingredients which are the so-called active ingredients. Maybe it is impossible to list all of the ingredients. Certainly it wouldn't be possible with a perfume.

The CHAIRMAN. Then it would be helpful in the treatment of the patient, in the event anything should occur, to have the ingredients specified in the labeling?

Dr. PECK. Yes, sir.

The CHAIRMAN. With that information.

Dr. PECK. I certainly believe it would.

The CHAIRMAN. But from your experience, would a user be apt to read the labeling or a piece of paper that contained that information?

Dr. PECK. That is a very rare user who bothers with that at all.

The CHAIRMAN. That has been my experience.

Dr. Hedrick?

Dr. HEDRICK. Doctor, several months ago my wife developed a very painful finger, that is, the nail of the finger. I think it is the index finger of the left hand. I examined her finger and found there was fluid being collected under the nail. I also found she used this base coating.

I just wondered how that fluid got into the central part of that nail, right in the center of the nail. It wasn't around the edges or cuticles, it seemed to start right in the center of the nail.

Dr. PECK. That's a very interesting point you bring up, because I don't believe that with all the publications we have at hand including a symposium held on that subject at the American Academy of Dermatology sometime past anybody explained how that accumulation of fluid developed under the nail with apparent freedom around the edges.

Now there were several theories advanced. One was that the operator forced it in there. That didn't offer an explanation to me.

Perhaps what happened is that that particular base coat had some very peculiar properties of penetration and sort of wheedled its way and finally, was accumulated in the center of the nail bed. You know one of the explanations for brittleness of the nail is not that the nail polish removers remove the fat, but that by putting on a lacquer which is what nail polish is, you didn't allow for evaporation through the nail. Evaporation does occur even though you think that the nail is impermeable. Actually what happened, I believe is the combination of an irritating combination, if they still used a base coat plus a lacquer which prevented evaporation resulted in fluid under the nail.

Perhaps this is a much better explanation than some of the others that have been offered. But be that as it may, nobody quite knows.

Dr. HEDRICK. Have you had any patient who lost the nail completely from the use of this base coat?

Dr. PECK. I have had quite a few patients whose nails came off, but, as I recall, I don't remember one instance where the nail didn't come back.

Now, I will say that there was one patient who had one nail that didn't grow back, but I think it is because the doctor had made a wrong diagnosis of a fungus infection and removed the nail and scraped the base. But most of those cases, as far as I know, all of them in my practice, the nails came back. Some of them had quite a bit of to-do about it, though.

Dr. HEDRICK. Doctor, people vary in hypersensitiveness to chemicals and drugs. One patient may be hypersensitive to one particular drug or chemical which perhaps many others could use without being affected.

Dr. PECK. That is correct.

Dr. HEDRICK. How are you going to handle that situation with all these cosmetic preparations?

Dr. PECK. The situation is even more complex than that, Dr. Hedrick.

We are running now into the question of cross-sensitization. I hate to bring up this word now. It is complex enough. But very many chemicals have a common nucleus, and unless that is properly evaluated, you may think you are using something entirely different and develop an eruption following sensitization of one chemical because you used something that was similar. Let me explain that, and that is a situation which will take a great deal of discussion.

For instance, everybody now uses antihistaminics. Very few people know that if you become allergic to some antihistaminic, you may become cross-sensitive because of the similarity in the nucleus to novocain and sulfa drugs. So that somebody who develops a rash from the antihistaminic will suddenly find after taking a sulfa drug or being injected by their dentist with novocain that there will develop an eruption, because of an unsuspected cross-sensitivity.

Those are the kind of facts that have to be disseminated to the medical public. But to answer your question directly, in the majority of the cases, without taking this new complex facet into consideration, I would say that if you test enough people—we have found practically during the war in cosmetics, in chemicals, which came in contact with the skin, that if we tested enough people in a usage test or by repeated patch tests, statistically we could predict what would happen. Actually, we had the Army statistical service draw us up graphs.

For instance, if you use a thousand people and you test them and only one out of a thousand develops any sensitization, then it was fairly safe. If, let us say, out of 200 or 300 people none developed it, or only 1, in the average case it was absolutely safe. But as soon as you got 1 out of 200 and you could repeat it on the next 200, then that is a very sensitizing chemical.

Dr. HEDRICK. Doctor, what is your opinion of the use of estrogenic hormones in face creams? Do you think it is perfectly safe to use them?

Dr. PECK. That is a very interesting question. I think that the best way to answer that is the question of how much is in the cream—how much estrogen is in the cream.

Now hormone creams have been used for many years and, of course, as you are well aware, that has been a subject of a great deal of controversy about the possible dangers.

I think in a dosage of 7,500 to 10,000 international units per ounce, there has not been sufficient or there has been no evidence of enough systemic absorption to warrant barring them from the general public use.

Now in doses above that. I think that we have to be very cautious in advising people in their use.

Dr. HEDRICK. Do you believe anything above 10,000 international units per ounce, possibly, should be by prescription only?

Dr. PECK. I would say that if my opinion would carry enough weight so that I had a decision to make, I would rather say yes. I would like above 10,000 units to be on prescription. Not that I have any evidence how much above 10,000 that would cover.

Dr. HEDRICK. Have you actually seen any improvement on the skin in elderly people who had wrinkles from the use of creams of this type?

Dr. PECK. Let me put it this way: I have been acquainted with a large series of tests where hormone creams were used to see if you could stop or prevent aging of the skin. Most women who use hormone creams, if they are above the age of 50, I think their wish is father to the thought. I think they don't become young again. And they can spend all the money they wish.

Also, if you were to ask my opinion whether a woman who begins to use hormone creams at 35 will still look 35 by the time she is 50, I will say no. Now these are the extremes.

However, hormone creams have been apparently proven to do certain things. And there is controversy here, too. In reading the literature of the changes that occur after the use of hormone creams, good scientific authorities seem to have brought out that there is a little increase in the thickness of the epidermis, and there is a plumbing of the collagen fibers below the epidermis. That would account

for the fact that you see some improvement in women who use hormone creams in the lessening of the dryness and in apparent decrease in wrinkling.

It is like everything else. It can be proven physiologically that water has been taken up by the collagen after hormone creams. I think that while there is some improvement, the physiologic tests and the histologic tests are perhaps better in proving how good the hormones are than actual clinical observation.

To boil it down, I would say some changes are there, but they certainly take keen observation to determine the percentage of change.

I am not trying to weasel my way out of the question. I think there is some change.

Dr. HEDRICK. Do you believe there is any connection between estrogenic hormones and pithelioma or skin cancer?

Dr. PECK. That I would like to answer positively as no, because I have never seen it. I think that the evidence presented to me, which people obtain from rats can't be connected over to human experimentation. And nobody has shown, I think, in the range of 7,500 to 10,000 international units per ounce that it has given rise to any pithelioma.

As a matter of fact, senile keratosis, which I have classified in a book that came out in June as one of the precancerous dermitoses, has been improved by the use of cream containing hormones. Not that I prescribe them, but among my patients, women use the hormone creams, and I haven't seen any damage. I have seen lessening of dryness of the skin. You must not forget these were very good lubricating bases.

Dr. HEDRICK. That is all.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. Dr. Peck, we appreciate your testimony. What we are trying to do is to find out safe ways a new product or a new chemical can be certified for use.

You make a couple of very practical suggestions here, but the committee would like to know who you feel should evaluate or certify the tests that you suggest be done with a new product or new chemical. Who should do that work? So that we may make the tests, and then we can evaluate them, and we may say, "This is so," and in case of injury or a court case, we will have something and be able to say now this is certified to be so.

You suggest these tests should be made. What we want to know is who should make them and how are we going to say after they have been made that they have been properly evaluated.

Dr. PECK. Let me make this suggestion, if I may, which won't be a burden to the Government in adding to the payroll and would be very practical, because it has been done during the war.

Before I became a commissioned officer in the Public Health Service, I was consultant to the United States Public Health Service.

Let us have qualified personnel, like qualified toxicologists and qualified dermatologists supervise the tests, and then perhaps you could have as part of the Food and Drug Administration, or whoever is going to take charge of this new regulation——

Mr. HORAN. May I interrupt there?

Dr. PECK. Please.

Mr. HORAN. Would you have the Food and Drug Administration or would you have the Public Health Service do this?

Dr. PECK. I don't think it makes much difference. But what I was going to suggest is that you have——

Mr. HORAN. Some of us think it does. We feel that the Food and Drug Administration is an enforcing agency, and if the evaluation is going to be made, perhaps it should not be made by the enforcing agency.

Dr. PECK. As an officer of the Public Health Service, in association with Dr. Schwartz—I did a great deal of the evaluation.

Mr. HORAN. You probably want to say then that the Public Health Service is better qualified.

Dr. PECK. Yes, the Public Health Service. I was going to suggest that the Public Health Service can have civilian consultants.

Mr. HORAN. They do.

Dr. PECK. They do, who would help them in this.

Mr. HORAN. In other words, it would be the Public Health Service who perhaps would supervise this?

Dr. PECK. Yes.

Mr. HORAN. And you are aware of the work that the American Medical Association is doing through its committee on cosmetics, is that right?

Dr. PECK. I am.

Mr. HORAN. It is a very intriguing enterprise that the American Medical Association has. Don't you feel that the work it is doing should be credited in this field?

Dr. PECK. By all means.

Mr. HORAN. How would you make sure that that work which they are doing is credited, by having it so certified through the Public Health Service or something like that?

Dr. PECK. Yes. I think that would be a very practical method. We have the committee on cosmetics, and we also have the committee on irritants in the AMA, which I am on. We would then have our report, and we would confer with the United States Public Health Service, and I think we could come to some conclusions, because you see, the committee of the American Medical Association, I think, is best qualified to judge, perhaps, on the qualification of the dermatologists and the other people who are supervising some of the tests.

Mr. HORAN. That is all. Thank you, Dr. Peck.

Mr. KLEINFELD. I have one more question.

The CHAIRMAN. Dr. Kleinfeld.

Mr. KLEINFELD. In your opinion, Doctor, are these two situations different or comparable—suppose you have a cream containing 10,000 international units of hormones per ounce recommended for use on the face and neck. That is one situation.

The other situation is one which encompasses the use of that same product containing 10,000 international units per ounce for use on the face and neck, and also three or four other preparations, each containing 10,000 international units per ounce, for use as a shampoo lotion, and as a hair conditioner, and so forth, for use on your arms, hands, shoulders. So that a woman may be using all those preparations 24 hours per day. Does that latter situation present a different problem in your opinion, Doctor?

Dr. PECK. It certainly does. Now I should qualify that 7,500 to 10,000 units in an ounce, with instructions that the whole complete use of that amount should take place in about 3 weeks, then I am talking statistically about seeing no toxic effects from that amount of estrogen.

Now if that amount was to be rubbed in over the whole body every day, and an ounce used every day, I don't know what would happen under those conditions. I am talking about the use of that amount over a period to time of about 3 weeks to a month.

Mr. KLEINFELD. No other questions.

The CHAIRMAN. Thank you, Dr. Peck.

Dr. PECK. Thank you, gentlemen.

The CHAIRMAN. The next witness.

Mr. KLEINFELD. Dr. Walzer.

The CHAIRMAN. Your name and address, Doctor.

Dr. WALZER. Matthew Walzer, 20 Plaza Street, Brooklyn, N. Y.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF MATTHEW WALZER, M. D., BROOKLYN, N. Y.

Mr. KLEINFELD. Dr. Walzer, where did you obtain your medical degree?

Dr. WALZER. Cornell University.

Mr. KLEINFELD. What year?

Dr. WALZER. 1919.

Mr. KLEINFELD. What have you specialized in?

Dr. WALZER. Allergy.

Mr. KLEINFELD. For how long?

Dr. WALZER. Thirty years.

Mr. KLEINFELD. Are you a fellow of the American Medical Association?

Dr. WALZER. That is right.

Mr. KLEINFELD. Are you certified as an allergist by the American Board of Internal Medicine?

Dr. WALZER. That is right.

Mr. KLEINFELD. And you are a member of the American Academy of Allergy?

Dr. WALZER. Yes.

Mr. KLEINFELD. Have you contributed papers to the professional publications in the field of allergy?

Dr. WALZER. Yes, sir.

Mr. KLEINFELD. About how many, would you say?

Dr. WALZER. Seventy-five.

Mr. KLEINFELD. So for many years you have been a practicing allergist?

Dr. WELZER. That is right.

Mr. KLEINFELD. Will you please read your statement?

Dr. WALZER. This statement does not contain anything concerning purely dermatologic problems which, I believe, belong in the domain of the dermatologists. I will merely try to bring out a few points which I think need saying from the point of view of the allergist.

From the allergist's point of view, there is urgent need for modification of the present regulations pertaining to the manufacture and sale of cosmetics under the Food, Drug, and Cosmetic Act of 1938.

The allergist sees many cases of sensitivity to cosmetics. Although the majority of these are patients with dermatitis of a relatively mild nature, there are many who are made severely ill by the application of certain cosmetic chemicals, leading, in rare instances, even to fatalities. Moreover, sensitization to some chemicals, such as coal-tar dyes, may lead to chronic illness, since the sensitive patient cannot avoid encountering these dyes daily in wearing apparel, fabrics, furniture, and numerous other articles in his environment. Sensitization to sunlight is another serious complication which has resulted from the use of certain cosmetics.

Many have the impression that allergy affects only a very small part of the population, and that it is really a personal problem based on the patient's inherited predisposition to become sensitive. This concept is erroneous in relation to sensitivities resulting from the application of chemicals to the skin, as in the case of cosmetics. Most of the population, regardless of age, sex, or other allergic tendencies, are susceptible in varying degree to this contract type of allergy.

True sensitization to chemicals is not a matter of physical or chemical irritation of the skin. It involves a special mechanism in which the concentration of the material, the frequency and duration of the application, and, most of all, the particular sensitizing (antigenic) capacity of the substance play a part. Chemicals with a high skin-sensitizing capacity, should be prohibited from use in cosmetics and cosmetic procedures. The measures recommended for prevention of severe allergic reactions from coal-tar hair dyes by preliminary skin-sensitivity tests have proven totally inadequate. Making the test adequate would render it impractical.

Cautionary warnings on labels against possible dangers in the use of these dyes have also proven inadequate and unsatisfactory, since most users, even after reading these statements, do not grasp the full significance of the risks involved.

The fact that cosmetics frequently cause types of allergic reaction other than contact dermatitis is frequently overlooked. Symptoms of asthma and allergic rhinitis are commonly produced in the atopic (hereditarily predisposed) sensitive individual by substances in cosmetics which precipitate symptoms, either as a result of inhalation or of absorption through the skin. With certain chemicals, these symptoms may be extremely severe.

Because of the dangers involved, desensitization treatment with drugs and chemicals is not generally practiced, and when tried is usually of limited value. The patient who is sensitive to drugs and chemicals must usually depend on avoidance of contact to keep free of symptoms. Under these circumstances, the need for more detailed labeling of the constituents of cosmetics is most urgent.

While medical authorities may disagree as to what constitutes adequate pretesting of a new cosmetic, there is, nevertheless, common agreement as to the need for additional Federal regulatory legislation in connection with the manufacture and sale of cosmetics to meet the inadequacies of the Food, Drug, and Cosmetic Act of 1938.

The above remarks express my personal opinion. However, as Secretary of the Research Council of the American Academy of Allergy, may I express to this committee, as we already have to the Food and Drug Administration, our willingness to cooperate in any way possible to help in the solution of these problems.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Walzer, you say that chemicals with a high skin-sensitizing capacity, such as coal-tar dyes, should be prohibited from use in cosmetics and cosmetic procedures and that the measures recommended for prevention of severe allergic reactions from coal-tar hair dyes by preliminary skin-sensitivity tests have proven totally inadequate.

The present Food, Drug, and Cosmetic Act, section 601 (a), provides that a cosmetic shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or under customary or usual conditions of use.

The section says that that shall not apply to coal-tar hair dyes, the label of which contains the legend "Caution—this product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so may cause blindness."

What is your opinion of that provision of the act, if I have made it clear to you?

Dr. WALZER. Well, as I see it, this direction for preliminary skin testing hasn't proven adequate, because it has been left to the operator to do. And usually, if it is done at all—most of the time I believe it is not—it is read in 24 hours. But that doesn't tell very much. A test when done properly should be watched for at least 48 to 72 hours, and read after another interval of approximately 3 days.

In other words, 5 or 6 days are needed before one can say that sensitivity to the tested dye does not exist. But even that is inadequate because it doesn't take into consideration the possibility that the very test which you apply may produce sensitivity, and to determine that you have to wait another 2 weeks.

Mr. KLEINFELD. And do you think the ordinary beauty shop operator is qualified to make and properly read those tests?

Dr. WALZER. I certainly do not.

Mr. KLEINFELD. You say also, Doctor, that precautionary warnings on labels against possible dangers in the use of these dyes have also proven inadequate.

In your opinion would a simple direction constitute an adequate warning or caution?

Dr. WALZER. I don't think so.

Mr. KLEINFELD. In discussing the need for more detailed labeling of the constituents of cosmetics, do you believe that there is a need for a more detailed labeling of both the active and inert ingredients or merely the active ingredients?

Dr. WALZER. Well, I certainly think that we ought to ask for labeling of the most active ingredients. I suppose there is hardly any substance which may not cause an occasional difficulty. But I think if we asked for the labeling of those that are commonly or most apt to produce reactions, I think that would be reasonable.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Hedrick.

Dr. HEDRICK. Dr. Walzer, about how many chemicals would there be in ordinary cosmetics?

Mr. WALZER. That I could not state.

Dr. HEDRICK. Several hundred of them, would there not?

Dr. WALZER. I should imagine it might in the entire list of cosmetics, but in any particular product it might be only two or three, possibly only one or none.

Dr. HEDRICK. What ones, in your experience, are the most likely to cause these conditions?

Dr. WALZER. I think the hair dyes are the most troublesome, particularly the paraphenylenediamine dyes. Among inhalents orris root is the commonest.

The point I want to bring out here is that the allergic patient doesn't stand a chance because he doesn't know where those offenders occur or where they are being used.

Anybody who is sensitive to paraphenylenediamine dyes and common allergies knows what a difficulty it is to avoid these products. And I think a patient who is sensitive certainly would appreciate being able to read a label telling them that the ingredient is there.

Dr. HEDRICK. The usual allergic rashes that you get from the use of chemicals, would you call that a dermatitis?

Dr. WALZER. Well, they may all be called dermatitis if they involve inflammation of the skin, if I understand the term "dermatitis." But as the dermatologist has told you, there are different kinds of dermatitis.

Dr. HEDRICK. You mean a difference in appearance of the rash, depending on the chemical used?

Dr. WALZER. Not necessarily in the appearance of the rash, but in the process which is causing the rash.

Dr. HEDRICK. That is all.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. Dr. Walzer, you begin your statement with the assertion that there should be a modification in the present Food, Drug, and Cosmetic Act. And you understand that is what we are trying to arrive at. Now you recommend directly that coal-tar dyes be refused the open market?

Dr. WALZER. I beg your pardon?

Mr. HORAN. I say you recommend directly that coal-tar dyes be refused the open market in the United States. Is that your recommendation?

Dr. WALZER. Well, certainly in some of the uses that they are employed cosmetically, they should certainly be prohibited.

Mr. HORAN. What other modification in the existing law of 1938 do you recommend?

Dr. WALZER. Well, I have no prepared statement on that. I do feel, however, that the general application of principles as they apply to drugs should be applied to cosmetics. I don't think that the purpose of the chemical should be stressed, but its effect upon the body. The body doesn't know the difference as to whether a drug is being used as a drug or a cosmetic; its reaction is the same.

Mr. HORAN. Then your recommendation specifically is that the law be broadened to include cosmetics as well as drugs?

Dr. WALZER. That is right.

Mr. HORAN. That is all.

The CHAIRMAN. Thank you, Doctor.

Mr. KLEINFELD. Is Dr. Larson here?

Mr. LARSON. Yes.

The CHAIRMAN. Your name and address.
Mr. LARSON. Carl Larson, 681 Fifth Avenue, New York City.
(The oath was administered by the Chairman.)
The CHAIRMAN. Proceed.

TESTIMONY OF CARL LARSON, PH. D., CHEMIST, ELIZABETH ARDEN SALES CORP., NEW YORK, N. Y.

Mr. KLEINFELD. Dr. Larson, what is your position with the Elizabeth Arden Co.?
Dr. LARSON. I am the chemist in charge of manufacturing and research.
The CHAIRMAN. Speak a little louder, please.
Dr. LARSON. Chemist in charge of manufacture and research.
Mr. KLEINFELD. In our wire to Elizabeth Arden of December 7, 1951, we asked that you read a prepared statement setting forth the various products which Elizabeth Arden manufactures or distributes. Have you done so?
Dr. LARSON. I have brought with me a price list which gives all those products.
Mr. KLEINFELD. Please speak up.
Dr. LARSON. I have brought forth a set of our wholesale order forms which include all our products.
Mr. KLEINFELD. Does it include all your ingredients?
Dr. LARSON. No, sir, it does not.
Mr. KLEINFELD. We did ask you for a list of your ingredients, too, did we not?
Dr. LARSON. That is correct. We misinterpreted your telegram. We thought that since you also asked for a method of testing the various ingredients, which might run into volumes of testimony, and we thought you didn't want that, we prepared a short paper.
Mr. KLEINFELD. The telegram asked you to set forth the ingredients contained in the products. Isn't that clear enough?
Dr. LARSON. It is clear.
Mr. KLEINFELD. Have you a list of your ingredients?
Dr. LARSON. No, sir; I do not.
Mr. KLEINFELD. Is there any reason why you don't want to furnish the ingredients?
Dr. LARSON. I would first have to have permission of my superiors before I could give those to you.
Mr. KLEINFELD. Haven't you discussed it with your superiors since December 7?
Dr. LARSON. I previously stated I misinterpreted what your telegram stated.
The CHAIRMAN. Do you understand it now, Mr. Larson?
Dr. LARSON. Yes, I do.
The CHAIRMAN. You are directed to supply this committee with the list of ingredients.
Dr. LARSON. I understood the telegram was in the form of a request.
The CHAIRMAN. You now receive a personal direction to supply them to this committee.
Mr. KLEINFELD. Unless you wish to subpena them, Mr. Chairman.
The CHAIRMAN. It is directed now.

(The list of ingredients was subsequently submitted to the committee.)

Mr. KLEINFELD. We also asked you, and I quote, "to give us a detailed description of tests you perform on your products prior to marketing."

Dr. LARSON. What is that?

Mr. KLEINFELD. A description of the tests you perform on your products prior to marketing.

Dr. LARSON. That I have done.

Mr. KLEINFELD. In your statement here?

Dr. LARSON. I believe so.

Mr. KLEINFELD. Will you please read your statement, and we will see if those tests are set forth therein.

Dr. LARSON. Elizabeth Arden welcomes this opportunity of appearing before the committee to explain in detail how a new preparation is created, tested and tried before it is placed on the market alongside other Elizabeth Arden products which have stood the test of time and which have permitted this name to grow into a symbol of leadership.

It is a distinct pleasure for a chemist to work in the Elizabeth Arden laboratories for certain advantages are presented which make his position unique. When a new preparation is in the development process, there is no restriction as to the cost of the ingredients which might be included in the formula. The unwritten motto is "the best at any cost." From these best ingredients a product is formulated together with the personal evaluation of each experiment by Miss Elizabeth Arden, herself. One by one each experiment is tried by Elizabeth Arden on her own skin and changes are constantly made until the right texture, color, odor, and other properties are to the personal satisfaction of Miss Arden. Up to this point there is only the closest collaboration between the laboratory and Miss Arden.

Now a rigorous testing program begins with our salons. Since Elizabeth Arden has beauty salons in New York, Chicago, Philadelphia, Washington, San Francisco, and other large cities in this and other countries of the world, advantage is taken of the criticisms and evaluations of our operators, most of whom have been trained in the New York salon under the personal supervision of Miss Arden. Samples of the preparation under test are sent to all the salon operators, who, after a use test on themselves only, write to Miss Arden directly of their reactions. It is needless to say that this testing group of salon workers runs into the hundreds.

At the Elizabeth Arden factory there is another testing group of several hundred women. Naturally, they are interested in new developments and are quite anxious to try new products. Those who wish to try a proposed new product are given samples and a simple questionnaire to fill out.

If from any of these groups there is shown to be a person or persons sensitive to the product under test, then an investigation is started to find out what ingredient was responsible. A reformulation is made eliminating the objectionable ingredient and the testing program is repeated until such time that it is given a complete bill of health.

Genuine enthusiasm for the product is reflected in requests for bulk shipments to the various salons. These shipments are made only at the end of the testing program. The salons will then begin to use the

product on clients. The time of use on clients will extend into months before the product becomes available on the market. For example, a new liquid shampoo will soon be on the market whereas it has been in constant use in the salons for over 6 months. To this date no type of sensitivity or allergy has been reported or observed regarding this product.

Once a product has definitely been accepted into the Elizabeth Arden line then it is a problem of raw materials and manufacturing. The purchase and testing of raw materials are under the direct control of the laboratory. The laboratory is staffed by several chemists, each of whom has at least one degree from a recognized college or university. One of these chemists runs the control laboratory where all raw materials are tested prior to their use. Whenever an ingredient is used in a formula where the potency must be carefully controlled, it is placed under the direct control of the laboratory. Such is the case when hormones are added to Joie de Vivre, a hormone cream. The hormones are weighed and dissolved in the laboratory by a chemist and the solution is added by him to the batch. After the batch is completed, it is sampled and checked by an outside biological laboratory for potency before it is released for sale.

The manufacturing is carried out by well-trained operators under the constant surveillance of the foreman, a man with over 20 years' experience in the Elizabeth Arden factory. The foreman checks all the weights of the various raw materials, temperatures, and other critical factors particular to the many Elizabeth Arden preparations. Every batch is sampled and sent to the laboratory for test and approved before it is packaged. A green acceptable label must be issued by the control laboratory for every batch before it can be packaged. The samples submitted to the laboratory are kept for at least 3 years before they are destroyed.

The method of manufacture and the equipment used are adapted to the nature of the product being manufactured. For example, in the manufacture of Ardena special eye lotion all of the apparatus used and the method of manufacture are built around the demand of the finished product that it be sparkling clear and sterile. First, a room was selected that would be used for this type of product and nothing else. Proper filters were installed to filter the incoming air and sterile lamps placed in the area so that the air remains clean and sterile. An electric oven is part of the equipment to sterilize the bottles after they are washed free of dust and lint. After the eye lotion has been properly compounded and checked by the laboratory, it is put through a series of filters which sterilizes it while it is being filled into the bottles.

From the foregoing description of the birth and development of new Elizabeth Arden preparations and of the subsequent routine manufacture of established products, it is quite obvious that a great deal of care is taken not only to protect this great name but also the health, beauty, and loveliness of its users.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Will you please pass up that list of products?

Dr. LARSON. Yes, sir. [Handing document to Mr. Kleinfeld.]

Mr. KLEINFELD. Doctor, you mention on the first page of your statement the fact that your unwritten motto is "the best at any cost."

Dr. LARSON. Yes.

Mr. KLEINFELD. And—

from these best ingredients a product is formulated together with the personal evaluation of each experiment by Miss Elizabeth Arden herself. One by one each experiment is tried by Elizabeth Arden on her own skin.

Who is Miss Elizabeth Arden?

Dr. LARSON. She is the president and founder of Elizabeth Arden Sales Corp.

Mr. KLEINFELD. Is she a chemist?

Dr. LARSON. No, sir; she is not a chemist.

Mr. KLEINFELD. What kind of a test does she evaluate?

Dr. LARSON. What she feels is a beauty preparation.

Mr. KLEINFELD. I see. It has nothing to do with safety or anything like that?

Dr. LARSON. No, sir.

Mr. KLEINFELD. You say you began a rigorous testing program in your own salons. What kind of testing programs?

Dr. LARSON. Use tests.

Mr. KLEINFELD. By whom?

Dr. LARSON. By salon operators on themselves.

Mr. KLEINFELD. And on whom do they experiment?

Dr. LARSON. On themselves.

Mr. KLEINFELD. Under anybody's supervision?

Dr. LARSON. These are trained beauty operators.

Mr. KLEINFELD. Who trains them?

Dr. LARSON. They are trained in our New York salons; and, as I stated, under the personal supervision most of the time by Miss Arden.

Mr. KLEINFELD. Does any dermatologist watch the results of the use tests performed on themselves by these salon workers?

Dr. LARSON. Salon operators evaluate the results themselves, together with that of Miss Arden, together with that of the various members of the laboratory.

Mr. KLEINFELD. Who are the members of the laboratory? What do they consist of?

Dr. LARSON. They consist of chemists.

Mr. KLEINFELD. Anybody else?

Dr. LARSON. No.

Mr. KLEINFELD. You don't employ dermatologists at all?

Dr. LARSON. Only in an advisory capacity.

Mr. KLEINFELD. He is not there regularly at all?

Dr. LARSON. No, sir; he is not.

Mr. KLEINFELD. Nor any medical doctor?

Dr. LARSON. No, sir.

Mr. KLEINFELD. The methods of testing you specify, do they apply to all your products before you market them?

Dr. LARSON. They refer to all products; yes.

Mr. KLEINFELD. When you put out a shampoo, do you put the shampoo in the eyes of any animals first?

Dr. LARSON. This product that I mentioned has been tested.

Mr. KLEINFELD. In that fashion?

Dr. LARSON. Yes; it has.

Mr. KLEINFELD. When was this done?

Dr. LARSON. I can't remember exactly, but it is several months ago.

Mr. KLEINFELD. Can you remember whether it was done before the product was marketed?

Dr. LARSON. The product has not been marketed as yet.

Mr. KLEINFELD. Do you make any other shampoo products?

Dr. LARSON. We make one other shampoo product which is sold.

Mr. KLEINFELD. When did you put that out?

Dr. LARSON. On a guess I would say about 3 or 4 years ago.

Mr. KLEINFELD. Did you make eye tests before you put that out?

Dr. LARSON. There were only use tests performed on that particular shampoo. It has been since tested on animals.

Mr. KLEINFELD. In connection with your camomile shampoo and your permanent wave for children, did you make any tests before you put those products out?

Dr. LARSON. Eye tests, sir?

Mr. KLEINFELD. Yes.

Dr. LARSON. There have been no eye tests performed on that, because this product has been on the market for several years and it is not a new preparation.

Mr. KLEINFELD. When you put it out, you didn't first make the eye test; right?

Dr. LARSON. When it was first put out?

Mr. KLEINFELD. That is right.

Dr. LARSON. No; it was not.

Mr. KLEINFELD. You put out a hormone hand cream, do you not?

Dr. LARSON. Yes, sir.

Mr. KLEINFELD. Do you make any recommendations on your label as to how much should be used?

Dr. LARSON. I am not familiar with the directions on the label.

The CHAIRMAN. You are the chemist, are you not, in the plant?

Dr. LARSON. What?

The CHAIRMAN. Are you the chief chemist?

Dr. LARSON. Yes, sir.

The CHAIRMAN. And you are not familiar with the labels?

Dr. LARSON. Well, sir, I mean it would be extremely difficult to remember the directions on every preparation we manufacture.

The CHAIRMAN. Aren't they prepared under your supervision or direction?

Dr. LARSON. That is true, sir; but one can't remember everything that one reads and approves.

The CHAIRMAN. What do they contain in general?

Dr. LARSON. That I can say, but exactly, I cannot. It says a person should apply a liberal amount to the hands and work it well into the skin.

Mr. KLEINFELD. It doesn't contain any warnings or directions against misuse, does it?

Dr. LARSON. No, sir. From my experience it is impossible to cover all the uses to which a customer might put a product. A person who has been in the industry for a number of years knows that if you want to guard against all the uses that a product might be put to you would have a tail hanging from each preparation.

Mr. KLEINFELD. Would it be a tail to put on your label "Don't use more than 1 ounce per night"?

Dr. LARSON. Pardon, sir?

Mr. KLEINFELD. Would it be a tail—that is the word you used—would it be a hindrance or difficult thing to accomplish to put on the

label a warning against misuse, saying, "Don't use more than a certain amount per night"?

Dr. LARSON. That answer is obviously "No."

Mr. KLEINFELD. Do you make soap?

Dr. LARSON. We sell soap. We do not manufacture it ourselves.

Mr. KLEINFELD. I have no other questions.

The CHAIRMAN. I notice some of your lotions, oils, and so forth here. What is Firmo-Lift lotion?

Dr. LARSON. That product I have no knowledge about, sir. It is not made by me. It is made by another chemist in Elizabeth Arden and has been kept secret from me also.

The CHAIRMAN. It is kept secret from you?

Dr. LARSON. Yes.

The CHAIRMAN. I understand you are the chief chemist.

Dr. LARSON. That is correct.

The CHAIRMAN. You don't know about this product?

Dr. LARSON. I know of the product, but its method of manufacture I do not.

The CHAIRMAN. Here is another one—Slenderlines lotion. What is that?

Dr. LARSON. That is a liquid lotion which is used by a client, used for application to various parts of the body.

The CHAIRMAN. For what purpose?

Mr. LARSON. It is an astringent type of lotion.

The CHAIRMAN. Does the name mean anything—Slenderlines?

Dr. LARSON. I do not know the derivation of the name. It has been in use long before my employ.

The CHAIRMAN. You were selected to come here to be helpful to this committee——

Dr. LARSON. I am trying to.

The CHAIRMAN. And you are not familiar with the two items I happen to pick out. I recognize that everyone wants to puff his products as much as possible, and you certainly did a good job, or whoever prepared this statement. But I don't think it was very helpful to the committee.

There are many other products here that have suggestive titles. I imagine "Slenderlines" and some of these other catchy names would help sell the article, but no one seems to know much about it.

You may examine, Dr. Hedrick.

Dr. HEDRICK. Does your company have a license to practice medicine?

Dr. LARSON. No, sir.

Dr. HEDRICK. It appears to me that with all these eye preparations you have here—eye drops, eye salve, eye cream, eye this, eye that—you should have a license to practice medicine if you are going to use all these preparations in the eyes of human beings.

What do you use all these eye preparations for? What is the idea of all of them?

Dr. LARSON. We are primarily manufacturers of beauty preparations, and it is the purpose of each one of these preparations to improve the appearance of the person using them.

Dr. HEDRICK. You mean the appearance of their eyes?

Dr. LARSON. If it is an eye preparation, yes, sir.

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Dr. HEDRICK. That is what we are talking about—eye preparations. You have a long list of them here. Is that to improve the looks of the eyelid or the eyeball?

Dr. LARSON. None of them are applied to the eyeball, sir; therefore, they must be used in around the eye area.

Dr. HEDRICK. Don't they get into eye?

Dr. LARSON. It is possible by a person not a good operator to get them into their eye. In such cases there has never been a case where any injury has resulted from such contamination into the eye.

Dr. HEDRICK. As a matter of fact, you have an eye lotion that you drop in the eyes of the customers; isn't that correct?

Dr. LARSON. That is correct, sir.

Dr. HEDRICK. That is not used on the lid then, is it?

Dr. LARSON. No, sir.

Dr. HEDRICK. Do you think you have the right to drop medicine into people's eyes without a license to practice medicine?

Dr. LARSON. We don't claim it to be a medicine, sir.

Dr. HEDRICK. What do you call it?

Dr. LARSON. Eye lotion.

Dr. HEDRICK. Are there any chemicals in it?

Dr. LARSON. Yes, there are.

Dr. HEDRICK. Anything besides water?

Dr. LARSON. Yes.

Dr. HEDRICK. Well, it is a preparation then?

Dr. LARSON. Yes, sir.

Dr. HEDRICK. Do you know what is in these preparations, any of them, that go in the eyes?

Dr. LARSON. In the eye lotion, I do.

Dr. HEDRICK. What is in the eye lotion, for instance?

Dr. LARSON. There are several essential oils, which are in extremely dilute solution, such as spearmint, camphor, birch. There is sodium chloride, a preservative, phenol mercuric borate. There are a few more chemicals of that same nature I can't remember exactly, but you have an idea what that formula consists of.

Dr. HEDRICK. What is the idea of dropping a lotion in the eye—is it to beautify the eyeball?

Dr. LARSON. This is an eyewash. It is used to refresh the eyes of the person using it.

Dr. HEDRICK. Off the record.

(Discussion off the record.)

Dr. LARSON. It is used many times during the day. For instance, if you had a tough time reading for several hours and you used the eye lotion, it might even make your eyes feel better.

Dr. HEDRICK. How expensive is this eye lotion? What does it cost to the public?

Dr. LARSON. It is on that price list you have, sir. I don't know offhand.

Dr. HEDRICK. That is all.

The CHAIRMAN. Mr. Horan, do you have any questions?

Mr. HORAN. I want to impress on Dr. Larson the fact that this committee is not trying to find out your trade secrets. We do have a responsibility of possibly recommending to the Congress legislation that may affect you and the industry you represent. You have been

very evasive and uncooperative. We have had some very fine witnesses.

Dr. LARSON. I have not tried to be evasive. When I stated, for instance, before that I have no knowledge of that preparation, that is the truth. If you wish to have another chemist present who has knowledge, that is another thing.

Mr. HORAN. That is all, Mr. Chairman.

The CHAIRMAN. You are excused.

Mr. KLEINFELD. Mr. Fuller, please.

The CHAIRMAN. Your name and address?

Mr. FULLER. George H. Fuller, plant manager, Harriet Hubbard Ayer plant, Lever Bros., 505 Park Avenue, New York.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF GEORGE H. FULLER, PLANT MANAGER, HARRIET HUBBARD AYER, LEVER BROS. CO., NEW YORK, N. Y.

Mr. KLEINFELD. Mr. Fuller, you appear here on behalf of Lever Bros. Co.?

Mr. FULLER. That is correct.

Mr. KLEINFELD. Please read your stateemnt.

Mr. FULLER. My name is George H. Fuller. I am the plant manager of the Harriet Hubbard Ayer plant of Lever Bros. Co. I am a graduate chemist and have 25 years experience as a chemist with Ayer.

Your committee has asked Lever Bros. Co. to provide a representative to appear at its hearings and present a statement with respect to the cosmetic products which Lever manufactures, the materials we use in such products, and our methods for determining and assuring the safety of such products, for their intended use. Our products are well known for their quality. We are happy to have the opportunity to participate in these hearings and talk to you about them.

Cosmetic products are marketed through two divisions of our company, the cosmetics division and the Pepsodent division. The more extensive of the two from the standpoint of number of products in the line is the cosmetics division which manufactures cosmetics and perfumes which are distributed nationally through retail outlets by Harriet Hubbard Ayer, Inc., a wholly owned subsidiary of Lever Bros. Co.

We also sell a large volume of cosmetic products through our Pepsodent division. These products are sold both to wholesale and direct retail accounts on a Nation-wide basis.

Both the Pepsodent and the cosmetics divisions have research and production facilities separately assigned to them, and also have the full cooperation and benefit of the research and production personnel and facilities of Lever. The research and development division of Lever Bros. Co., including research personnel assigned to the Pepsodent and cosmetics divisions, is made up of approximately 300 persons, over 50 percent of whom are graduate chemists. Among its various sections devoted to the many phases of product development and product improvement is a biological section, including an animal laboratory, and facilities for patch testing and similar investigations. In addition, we occasionally retain the services of recognized experts

in their fields to assist us in developing testing procedures and to conduct testing programs for us.

The manufacturing division has control chemists stationed at each plant location, in addition to the research and development personnel. These chemists are responsible for checking the conformance of raw materials and finished products to quality requirements as represented by our manufacturing standards.

A list of the materials used by the Pepsodent and cosmetics divisions in cosmetics manufacture is appended to the copies of this statement which have been furnished to the committee.

On my staff at the Ayer plant are two research chemists in addition to myself and one control chemist, all four of us having degrees of bachelor of science, two in chemistry and two in chemical engineering.

The cosmetics division manufactures creams, lotions, powders, and fragrances. At the present time, the line consists of 59 products exclusive of size and shade variations. There are 93 shade variations among 16 items, so that a total of 136 formulations are merchandised.

One hundred and twenty-three separate raw materials are used by the cosmetics division. Of these, 36 percent conform to specifications of the United States Pharmacopoeia; 6 percent conform to the specifications of the National Formulary and 31 percent are colorants either certified or not requiring certification by the Food and Drug Administration. The remaining 34 items have been carefully screened by us to insure that they are of innocuous character and suitable for use in cosmetic formulations.

Products are formulated by a competent cosmetic chemist who is thoroughly familiar with the action of cosmetic materials and their compatabilities with each other. He is of course cognizant of the proper specifications, concentrations, and other safe use properties of all common cosmetic materials. His task is to formulate a product having the desired use properties from both a cosmetic viewpoint and the viewpoint of consumer safety, using either well-known and widely accepted cosmetic ingredients or such new materials as are offered by reliable suppliers with suitable guaranties as to purity and safety. Whenever the new product entails the use of a material new to the established cosmetic industry, animal tests are made on it and on the finished product containing it. Data from animal experimentation is supplemented by human patch tests to evaluate mildness and sensitizing properties of the product.

Where the product developed by the cosmetics division is a new product category, either unknown or not fully established in the industry, the development and testing work, and results, are frequently reviewed with representatives of the Food and Drug Administration. Although they cannot give official approval to anything so submitted, the comments and viewpoints of the FDA staff are considered desirable and their unofficial suggestions, if any, are carefully considered. For example, in preparing for marketing two of our more recent products, Formulayer cream and Ayerfast lipstick, we reviewed them with the Food and Drug Administration. Some persons show allergic reactions to lipsticks of high indelibility. While the consumer thinks it desirable to have the stain, which the lipstick provides, remain for long periods, such lasting quality requires penetration of the stain into the skin, and where the formulation allows such penetration, the dyes used in these lipsticks appear to irritate

some persons. Of course, Lever did not desire to introduce such a lipstick without first finding a remedy for this problem. It was our opinion that the addition of an ingredient never before, to our knowledge, used in a cosmetic but having known useful properties in connection with allergic responses of various types, might overcome the irritating effect of lipsticks of this character. This material was accordingly added to lipstick formulations containing other usual lipstick ingredients and one of the most commonly used indelible lipstick dyes.

The resulting lipstick was tested on a panel of women, the greater number of whom were known to be allergic to lipsticks containing this dye. The results indicated that the ingredient which we added to the formula reduced the incidence of reactions from such lipsticks to a range approximating standard lipsticks.

As we have indicated before, this formula was reviewed with the Food and Drug Administration and they expressed no objection to the marketing of the product. After further extensive consumer testing, we marketed a complete line of Ayerfast lipsticks.

A similar procedure was followed in the case of Formulayer cream, the other new produce we have mentioned. Formulayer was developed so that we might market a product to compete with hormone creams. However, we felt that hormones as such might be shown to have some undesirable effects. We believe that the chemical structure of hormones was in some way related to the ability of skin to absorb oils and thereby set up a kind of barrier against loss of subsurface skin moisture, and that materials of related chemical structions which are not hormones should have the same effect. We selected a naturally occurring product having such a structure and formulated it with normal cosmetic ingredients. This new ingredient is completely safe even if taken internally and is recognized as an edible material. In the course of this work, we utilized the services of two well-known dermatologists to perform use tests on this product, Dr. Samuel Peck and Dr. Eugene Traub. We also arranged a meeting with members of the FDA staff at which we fully informed them as to the formulation and ingredients, the intended use of the product, and its proposed labeling.

The same care is observed in the development and manufacture of our Pepsodent products. The work is under the direction of Dr. S. D. Gershon, the research manager who has 21 years of chemical and pharmaceutical experience. He holds the degrees of pharmaceutical chemist, bachelor of science, master of science, and doctor of philosophy in chemistry and is a registered pharmacist. On his staff are approximately 30 people, 15 of whom are graduate chemists, 2 are dentists, 2 bacteriologists and 2 beauticians.

The Pepsodent division manufactures dentifrices, shampoos, hair, preparations, mouth wash, and Lifebuoy shaving cream. Most of these products or substantially identical ones have been marketed for many years without adverse results as to safety for consumer use. Regardless of this, each of them has been carefully tested by us for safety in accordance with our usual policy. Pepsodent's waving lotions, creme rinse, hair tonic, mouth wash, and Lifebuoy shaving cream, were all tested on animals and on humans, as was the active detergent ingredient of all Pepsodent dentifrices. The dentifrice formulations and the abrasive ingredients were tested first on extracted

human teeth, dental filling materials, and denture materials. The dentifrices were checked on hamsters, in clinical-usage tests, and in consumer-use tests. Our Rayve creme shampoo was studied with patch tests and use tests in the laboratory, and then on a consumer test.

The care with which new products are approached is demonstrated by our investigation of thioglycolate waving lotions. Lever purchased the line of Rayve products and Hedy wave from William R. Warner & Co., one of the leading cosmetic manufacturers in the United States, in 1948. Although thioglycolate lotions had been pronounced reasonably safe in a published article by members of the FDA staff in May 1947, and although all of these products had previously been marketed by a Warner subsidiary, we reviewed them from a safety viewpoint for many months.

The tests on the thioglycolate lotion included repeated subcutaneous injection into experimental animals to determine toxicity, patch tests on over 300 individuals, in excess of 500 waves given in the Pepsodent and Lever laboratories, including waves given under conditions of extreme overtiming, some of which were rewaved 10 days later, and over 1,000 consumer waves under actual-use conditions.

Rayve home permanent bears the seal of acceptance of the committee on cosmetics of the American Medical Association, and the seals of approval of the Good Housekeeping Bureau and of Parent's Magazine.

Our thioglycolate lotions and neutralizer are manufactured with careful controls. It has been our practice to analyze samples of the raw materials and the finished product and retain coded samples from each batch made.

Our new waving lotion, Shadow Wave, which is also a thioglycolate lotion, has likewise been extensively tested and is similarly controlled in its manufacture.

Your committee has also asked that we comment on toilet soaps. Lever toilet-soap products are sufficiently widely known and used and have been so known and used for so long a period that their safe-use properties are evident. They are composed principally of pure fatty acid soap, moisture, small amounts of perfume and preservative, and in the case of Lifebuoy a small percentage of specially refined cresol, a material recognized as having desirable qualities for skin treatment. Traces of coloring materials are also used, particularly in Lifebuoy. During the many years these products have been on the market they have been repeatedly tested in various ways on animals and humans in connection with various research projects designed to increase our knowledge of soap and of cleansing of the skin. Their production is controlled with the same high degree of care as is that of our cosmetic products.

It has been a pleasure to present this statement to you on behalf of Lever Bros. Co. As a reputable manufacturer of cosmetic products, we believe that safety is a primary consideration upon which the continued success of our business depends.

The materials currently used in manufacturing by the cosmetics and Pepsodent divisions of Lever Bros. are as follows:

[The list referred to is in the files of the committee.]

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Mr. Fuller, you mentioned in the last part of your statement that Lever Bros. makes toilet-soap products?

Mr. FULLER. That is true.

Mr. KLEINFELD. If Lever Bros. were to put out a new toilet soap tomorrow, would it put it through the same general tests you use in connection with your cosmetic lines?

Mr. FULLER. I have no question of that, although that is not within my jurisdiction.

Mr. KLEINFELD. You say you believe Lever Bros. would?

Mr. FULLER. Absolutely.

Mr. KLEINFELD. Is there any reason, in your opinion, for treating soaps differently from other cosmetics?

Mr. FULLER. I have assumed that toilet soaps represented cosmetics, and, yet, my own experience with them is so limited I don't think I would be qualified to answer that from the point of view of the company.

Mr. KLEINFELD. You said that you confer from time to time with the Food and Drug Administration?

Mr. FULLER. That is correct.

Mr. KLEINFELD. For what purpose?

Mr. FULLER. To present to them the complete background of any product we desire to put on the market which represents a new combination of ingredients we have not previously marketed.

Mr. KLEINFELD. Have you had personal contact with the Food and Drug Administration?

Mr. FULLER. That is correct; yes, sir, I have.

Mr. KLEINFELD. What has been your experience?

Mr. FULLER. It has been extremely cooperative.

Mr. KLEINFELD. I have here a book entitled "Historic Meeting To Commemorate Fortieth Anniversary of Original Food and Drugs Act," put out in 1946 by the Commerce Clearing House.

This meeting was held under the auspices of the section on Food, Drug, and Cosmetic law of the New York State Bar Association. At that meeting an address was made by H. Gregory Thomas, vice president of Bourjois, Inc. The address was entitled "Its"—speaking of the Food and Drug Act—"Basic Value to Cosmetic Industry."

In this address this is what was said in part:

> The stated and continuing policy of the Food and Drug Administration to give industry the benefit of administrative interpretations of the present law, in its effect on the legality of the composition or processes of production of a given cosmetic, has been most helpful to us, and we hope such a policy will continue in years to come.
>
> The informal decisions of the Administration on new or borderline questions which have been made available to industry members through letters and documents, which can be seen at several offices of the Food and Drug Administration, have also been a valuable source of guidance to manufacturers, and one which in turn facilitates compliance with, and enforcement of, the law.
>
> We have had occasion to note that it is the policy of the Food and Drug Administration "to avoid interference with the development or adoption of new products or processes that represent genuine advancements, and that are, therefore, in the interest of consumers." * * *
>
> We of the cosmetic industry subscribe to this view of a law that has grown, and we will continue to grow with our industry.

Is that general in line with your experience?

Mr. FULLER. It certainly has been.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. No questions.

Mr. FULLER. If the committee would like, one of the questions asked, I believe, was our general opinion as to our attitude toward possible legislation.

Mr. HORAN. That is the question I was going to ask you.

Mr. FULLER. Dr. Gershon, our director of research at Pepsodent, is with me here, thinking perhaps you had some questions relating to hair preparations which I was not qualified to answer. He is prepared to give you such a statement if you would like to hear it.

Mr. HORAN. You understand what we are trying to do is to arrive at the wisdom which can enable us to recommend to the Congress any possible modifications or enlargement of the present pure-food laws, and in doing that we want the help of gentlemen like yourself who have to produce in this field and who understand what we are trying to do. We are trying to do it very seriously, and understand the importance of the work we are trying to do. It is not sensational, nothing in that line. But what we recommend is bound to affect your daily lives and the responsibilities you have.

Mr. FULLER. Yes.

Mr. HORAN. And in that regard we want the very best thinking about what possible modifications should be made. I personally urge you folks to be frank with us on the benefits of your thinking.

Mr. FULLER. Mr. Horan, we have given considerable thought to your telegram, and for that reason Dr. Gershon is here, and we would like very much to have him read a statement. It represents the combined thinking of our whole research organization.

Dr. HEDRICK. I have one question.

The CHAIRMAN. Dr. Hedrick.

Dr. HEDRICK. I notice all the raw materials you use in cosmetics. Where do you get those raw materials and what do you do with them after you get them? What tests do you make on them?

Mr. FULLER. They are purchased to meet the specifications of the formulas which are already in existence in our line. In some cases we are searching the market for new materials, and each one of those new materials receives the same careful attention as to their chemical analysis and as to their use-testing properties when combined in a cosmetic formula. We cannot, of course, know what the result will be until such a formula is compounded and tested by our biological division.

Dr. HEDRICK. You usually buy them from reputable manufacturers, do you?

Mr. FULLER. That is correct.

Dr. HEDRICK. And you not only know what they say about them, but you go ahead and test them?

Mr. FULLER. Exactly. We get every bit of information that any company is able to supply us with, of course, before we even formulate a product. But in addition to that, we have our own program.

Dr. HEDRICK. That is all.

The CHAIRMAN. May I say, Mr. Fuller, that you received the same telegram or inquiry that all of the other witnesses received and your statement indicates a desire to cooperate.

Mr. FULLER. That is right.

The CHAIRMAN. And I want to compliment you, because it has been prepared with care and thought. And I, for one, found it most helpful, and I know my colleagues here feel that we got some benefit from the statement you made and the detailed care which is used by your company in testing new products. It has been helpful to me. Thank you.

Mr. FULLER. Thank you, sir.

Mr. KLEINFELD. Do you wish to hear Dr. Gershon?

How long do you think he will be, Mr. Fuller?

Mr. FULLER. Possibly 2 minutes.

The CHAIRMAN. Your name and address, sir?

Dr. GERSHON. Sol D. Gershon, Lever Bros. Co., 505 Park Avenue, New York.

(The oath was administered by the chairman.)

TESTIMONY OF SOL D. GERSHON, PH. D., REPRESENTING LEVER BROS. CO.

Dr. GERSHON. I was privileged to be present last Friday to hear part of the proceedings of this committee, and felt that in view of Mr. Horan's statement on Friday requesting concrete suggestions from representatives and witnesses, that perhaps we could help a little in preparing a statement. Over the week end this statement was prepared and was just typed this morning.

Though we recognize that legislation can be considered as one means of attempting to minimize even the small incidence of injury resulting from the use of cosmetics, we submit, respectfully, that because of the small incidence of injury; because legislation at best could only effect a partial solution; because of the financial and work burdens legislation would impose on the people of this country, the Government and industry; because additional money spent may be more helpful in the protection of the public in fields other than the cosmetic field, serious consideration should be given to using education, a tool used effectively and frequently in objectives comparable to the one under consideration at this time, as the means of attempting to accomplish a reduction in the incidence of injury from cosmetics.

We are suggesting to the committee that education, rather than legislation, be given careful consideration as the most promising means of minimizing injury resulting from the use of cosmetics.

The continued success of a business depends upon the safety of its products. This is true for every cosmetic manufacturer, large or small. The company which makes products which cause injury to the users of the products does not survive in business.

Whether for selfish reasons or not, every cosmetic manufacture desires that his products be safe. We believe that because of the continuous progress and developments in the sciences that are of concern to the cosmetic industry, more information—more education—would assist the manufacturer and his scientific representatives in this objective.

Hearings such as the one in progress are excellent for the industry because they furnish an opportunity to exchange thoughts on procedures designed to increase product safety. They publicize the safety theme and create an extra awareness of the ever present need for careful methods. They are "education" for the industry.

We believe that any consideration of a means to minimize injuries must take into account the extent of injury compared with the amount and extent of usage and what detrimental effects any proposed remedy may have. The incidence of injuries due to cosmetics appears to be exceedingly small in view of the size of the industry and the number of cosmetic products sold. It may be that legislation requiring approval of new cosmetics would prevent some of these injuries. On the other hand such approvals could lull some users into the belief that all cosmetics were accepted by the United States Government and as a result could make them less discriminating in their selection and use of cosmetic products, leading to the possibility of a greater incidence of injury.

The September 29, 1951, edition of the Journal of the American Medical Association includes an article which points out that 107 drug fatalities have been reported since 1946, deaths not from poisonings of the accidental or suicidal type but from the use of regularly advised and prescribed drugs. This was possible in spite of the stringent requirements of the Food and Drug Act as it applies to drugs.

The Food and Drug Administration can do an effective job under the present law to the end of minimizing injuries resulting from the intented use of cosmetics. The law provides penalties up to $10,000 fine and 3 years imprisonment, for its violation. Given adequate information on testing methods, no manufacturer will choose fine and imprisonment over a testing program. The FDA has developed suggested testing procedures as has the committee on cosmetics of the American Medical Association. More widespread publicity and education as to these recommended procedures is needed in the industry, so that with full knowledge of the work of others on products in the same field, a manufacturer can determine what testing his product may require. Continuous examination of manufacturing plants should be helpful in keeping manufacturers alert.

In addition to suggested testing procedures, any information indicating problems arising from use of certain ingredients or formulations which may come to the attention of the FDA, without restriction as to publicity, should be publicized to the industry. Such an effort will meet with widespread cooperation and acclaim. We feel that these hearings are a first step in this education process and again we say that we are pleased to have had the opportunity to participate in them.

The CHAIRMAN. Thank you.

Mr. KLEINFELD. Are you a medical doctor?

Dr. GERSHON. No; I am a Ph. D. in chemistry and a registered pharmacist.

Mr. KLEINFELD. Not a medical doctor or dermatologist?

Dr. GERSHON. Not a dermatologist, nor a physician.

Mr. KLEINFELD. You say, on page 2 of your statement, that it may be that legislation requiring approval of new cosmetics would prevent some of these injuries. Wouldn't that be a good thing?

Dr. GERSHON. Taken in itself, yes.

Mr. KLEINFELD. We want to keep down injuries as much as we can, don't we?

Dr. GERSHON. There is no question about that. Even one injury is one too many.

Mr. KLEINFELD. If we can prevent even one injury, we ought to try to do so, should we not?

Dr. GERSHON. Provided you are not contributing to more injuries in another direction.

Mr. KLEINFELD. That is right.

You follow by saying:

> Such approvals could lull some users into the belief that all cosmetics were accepted by the United States Government and as a result could make them less discriminating in their selection and use of cosmetic products, leading to the possibility of a greater incidence of injury.

What do you mean by that?

Dr. GERSHON. I mean if the general public got the impression that cosmetics were approved by the Food and Drug Administration and by the Government, they may take less care in reading directions and in discrimination as to the use, and therefore you might have even more accidents with respect to cosmetics.

Mr. KLEINFELD. You mean a requirement that a cosmetic be pretested to the satisfaction of the Government agency would make people careless?

Dr. GERSHON. It is conceivable.

Mr. KLEINFELD. Do you know that there is a new drug provision in the act which requires pretesting of new drugs?

Dr. GERSHON. Yes.

Dr. KLEINFELD. Do you think that has made people more careless in buying drugs?

Dr. GERSHON. Well, the answer there is, of course, they may not have to become more careless. I just read you the statement where even with good use of the drug, prescribed use of the drug, there is a great deal of possibility of injury.

Mr. KLEINFELD. Let me rephrase my question. Do you think that the new drug provision of this act, which requires that new drugs be pretested to the satisfaction of the Food and Drug Administration before they are used, has caused people to become careless in the use of drugs?

Dr. GERSHON. May I ask you a question?

Mr. KLEINFELD. Yes.

Dr. GERSHON. Are the new drugs that are passed by the Food and Drug Administration sold without a prescription?

Mr. KLEINFELD. Both with and without.

Dr. GERSHON. Both?

Mr. KLEINFELD. That is right. Now can you answer my question?

Dr. GERSHON. I should think in that particular case—well, I don't know the answer. How would I know whether or not there is more injury as a result of a certain drug having been tested or not?

Mr. KLEINFELD. How do you know people would be careless if manufacturers had to test cosmetics?

Dr. GERSHON. I didn't say they would be.

Mr. KLEINFELD. We have the experience of the new drug section, don't we?

Dr. GERSHON. I don't know that the answer there applies here.

Mr. KLEINFELD. Do you know there is a provision in the act which makes it a criminal offense for a new drug manufacturer to use on the label of a drug, or in any advertising relating to a drug, any representation that the product has been approved?

Dr. GERSHON. Yes; I know that.

Mr. KLEINFELD. Couldn't such provision be in the law with respect to cosmetics?

Dr. GERSHON. There could be such a provision, of course. I expect there would be. But if the general impression publicized was that the drugs were approved by the Food and Drug Administration, that is the cosmetics were approved by the Food and Drug Administration, it would have the same effect. If my argument holds at all, sir—and I don't know that it holds—but if it holds at all, it would have the effect whether publicized or not.

Mr. KLEINFELD. Doctor, you are suggesting to the committee—and this is apparently part of your statement—that education rather than legislation be given careful consideration as the most promising means of minimizing injury resulting from the use of cosmetics.

Suppose I want to put out a cosmetic tomorrow, and I am a small man and I have a bathtub. That's about all. I want to go into business. I put together some ingredients that I think are probably all right and I put my preparation on the market. Isn't there a possibility of injury?

Dr. GERSHON. Yes, I would say definitely there is a possibility of injury there.

Mr. KLEINFELD. How would education help that situation?

Dr. GERSHON. If there were education—first of all, let me make one point. I think you recognize that even the Food and Drug Act as it applies to drugs doesn't stop that. In other words, there are plenty of violators of the Food and Drug Act anyway. Therefore, you can have injury in the Drug Act just as you can in the Cosmetic Act.

However, the education will stop the number of people that would do that if it was publicized. Here is a man who had $10,000 fine and so many years in jail for doing it.

Mr. KLEINFELD. Isn't there a difference in the situations? In one case you have a law which says if you put out a product on the market and it causes injury, you are then subject to prosecution. Isn't it true that under such a law a manufacturer may say, "I think this is probably all right; therefore I will do it. If it is probably all right, I will be free from prosecution." Isn't that correct?

Dr. GERSHON. That is right.

Mr. KLEINFELD. The other type of law is one which requires that if you want to put a product on the market you must first show us it is safe—whether in fact it is good or bad.

Dr. GERSHON. That is right.

Mr. KLEINFELD. Does not the latter type of law minimize greatly the danger of injury because the manufacturer knows that whether he guesses right or wrong he is immediately subject to prosecution if he has not first submitted the requisite data?

Dr. GERSHON. I grant you that, Mr. Kleinfeld. However, you don't make laws in anticipation of what is going to happen. You make laws to prevent what you know is happening. In the cosmetic industry, if we admit the amount of injury is small, why make a law to prevent something the history of the industry hasn't shown is needed?

Mr. KLEINFELD. Your assumption is not the assumption held by most of the dermatologists.

The CHAIRMAN. We will give it a proper evaluation, I am sure, and we are indebted to you for your opinion.

Call the next witness.

Mr. KLEINFELD. Dr. Klarmann.

The CHAIRMAN. Your name and address?

Dr. KLARMANN. Emil G. Klarmann, Lehn & Fink, 192 Bloomfield Avenue, Bloomfield, N. J.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF EMIL G. KLARMANN, CHIEF CHEMIST, LEHN & FINK PRODUCTS CORP., BLOOMFIELD, N. J.

Mr. KLEINFELD. Dr. Klarmann, you are employed by the Lehn & Fink Products Corp.?

Dr. KLARMANN. That is right.

Mr. KLEINFELD. What is your position with that company?

Dr. KLARMANN. Vice president in charge of research, also director of research for the subsidiary companies of Dorothy Gray and Tussy Cosmetics.

Mr. KLEINFELD. Your training is in chemistry?

Dr. KLARMANN. That is right, and chemical engineering.

Mr. KLEINFELD. Please read your statement.

Dr. KLARMANN. Lehn & Fink Products Corp. produces four lines of cosmetic products, namely, Dorothy Gray, Tussy, Special Formula, also individual items under the Lehn & Fink name (Hinds cream, Etiquet deodorants, Peb-Ammo tooth paste). The most important of these lines is Dorothy Gray which is distributed by a subsidiary corporation known as Dorothy Gray, Ltd. Annexed hereto as exhibit A is a list of the items in the Dorothy Gray line. Annexed as exhibit B is a list of the ingredients used in these products. The Tussy and Consumers Special lines have similar products composed of the same ingredients.

The principal office of Lehn & Fink Products Corp. is at Bloomfield, N. J., where it maintains a manufacturing plant and complete research and analytical facilities. It also has a newly constructed manufacturing plant at Lincoln, Ill. The company believes that its success in the field of cosmetics is attributable largely to the extreme care it has always exercised in the preparation of its formulas and the rigid testing of the ingredients used in its products. The sale of cosmetics is based on public acceptance built up through advertising, attractive packaging, and an assurance of quality that will induce the customer to buy the product again. One defective product in a line, or perhaps a defective run of products in the line, will do inestimable damage to the reputation of the trade name. It is, therefore, of great importance to our company to be certain that every article that leaves our plants is absolutely safe for the uses for which it is advertised and will live up to the customers' expectations of quality and effectiveness.

For this reason the company has for many years retained as part of its executive organization a full time chemist with a staff of assistant chemists, bacteriologists and technicians who engage continually in analyzing and testing raw materials for purity and quality, and conducting an extensive program of research for the purpose of improving our present products and developing new ones. The laboratory itself is fully supplied with equipment designed to carry out this work in a thoroughly complete and scientific manner.

Every shipment of raw materials received at our plants is ordered according to stringent specifications prepared by our chemists, and after arrival it is subjected to careful analysis by the laboratory using modern scientific techniques. Any material which does not meet the specifications is rejected by the laboratory. As each batch of finished products is prepared, samples are carefully checked before packaging begins. The production department is not permitted to proceed with packaging of any batch until the laboratory has approved the sample. After packaging is completed, further samples are checked by the laboratory.

In addition, we support research projects at universities and other institutions, from time to time, for the purpose of testing new ingredients for quality and effectiveness. One such project is now in progress in a New York institution where a proposed ingredient is being tested with a view to finding ways of reducing its allergenic potential.

From time to time, as a check on our laboratory work, we submit our formulas to independent dermatologists for review and for their opinions as to the cosmetic effectiveness of the products. Their views are given great weight by our chemists in the selection of initial raw materials and in the preparation of finished products. In the case of new products, great care is exercised before placing them on the market to see that they are both effective and safe. If the new product is composed of well-known ingredients with an extensive and unquestioned record of safety, such as lanolin, mineral oil, glycerine and the like, no specific tests of their cosmetic characteristics are necessary. However, the product is nevertheless subjected to consumer use tests by personnel of the Dorothy Gray Salons, and frequently by the personnel of Good Housekeeping or other similar organizations.

On the other hand, where the new products call for the use of new chemicals, or for a new principle of application, careful tests are made by our laboratory and at the same time projects are established with independent dermatologists or other specialists, or with outside scientific institutions. The new product is not introduced on the market until it has met these tests and proved itself to be safe in all respects and effective for the purposes for which it is recommended. An example of this testing of new products in Cellogen cream, the Dorothy Gray brand of estrogenic hormone cream. This product contains 10,000 immunizing units of natural estrogenic hormones, and it is effective in improving the appearance and texture of the skin at the point of application, with no perceptible effect upon the system as a whole.

The marketing of products of this kind has been the subject of considerable controversy, the opposition in every case coming from persons who have never subjected the product or the principle to any scientific tests or analysis. Before introducing Cellogen cream and Cellogen lotion we established a research and testing project at an eastern university's medical school under the supervision of one of the country's leading dermatologists. Under the project the effect of the cream on the skin was carefully determined by subjects who used it regularly over a long period of time. Microscopic examination of the skin before and after use showed a definite local improvement in the condition of the skin structure, and general examination showed clear and marked improvement in the appearance of the skin. A well-known endocrinologist made tests to determine the effect on the rest

of the body and found no such systemic effect. Thus, the only effect observed was local, and this is understandable in view of the fact that the quantity of hormone applied on each use was infinitesimal as compared, for example, with the usual medical dosage.

These tests, as well as the literature on the subject of tests conducted by other recognized research scientists, showed conclusively that the prejudice against such products was unjustified. Consumer use of Cellogen over a number of years has confirmed the accuracy of our conclusions.

Many similar examples of the testing and anlysis of our products, over the years, could be given.

These analytical and research procedures are both elaborate and expensive, but we consider them to be absolutely essential to the welfare and progress of our business, to the preservation of the integrity of our trade-marks, and to the protection of our customers. In the last 10 years we have spent a total of about $1 million on laboratory and research work, using modern equipment, and employing chemists and bacteriologists with the highest skill and scientific training.

From a consumer viewpoint, our products have clearly stood the test. In the last fiscal year we have placed on the market about 30 million packages of cosmetics. Careful records have been kept of complaints which have come to our attention. Their total number during the same period of time is 106, or 0.0003 percent (1 : 300,000). This is so infinitesimal as to be wholly negligible. Also, we are confident that many of these complaints are due to other causes, and that it is only the consumer's unscientific guess which caused her to attribute the complaint to our product.

COMMENTS ON PROPOSED LEGISLATION

We understand that legislation has been proposed under which the new-drug provisions of the Federal Food, Drug, and Cosmetic Act would be extended to cosmetics. It seems to us that such legislation would be both unnecessary and unwise, for the following reasons:

(1) The provisions of the present Federal Food, Drug and Cosmetic Act with respect to adulteration of cosmetics furnish adequate protection to the public against the use of faulty ingredients. Cases of adulteration not prevented by the inhibitions of the act, or by the Food and Drug Administration's enforcement activities, are in most cases due to accidents which would have occurred irrespective of any administrative review by a Government agency. One cannot prevent accidents by legislation.

(2) The importance of quality and safety to the success of any cosmetic business furnishes a stronger incentive for care in the selection of ingredients than would legislation.

(3) The testing facilities and personnel of a Government agency are not likely to be better, and may be substantially less effective, than those of a private company which is necessarily anxious to avoid the use of any faulty ingredient that would destroy its business and its trade-marks. The analytical and research facilities of our company and those of the leading cosmetic manufacturers are of the highest character and quality (for our and their own protection respectively), and there is no reason to believe that an already heavily burdened Government agency could do better.

(4) If the laboratories of private cosmetic companies were burdened with the red tape of pretesting requirements, their efficiency, and effectiveness would be considerably reduced.

(5) If the Government assumes the responsibility of administrative review and approval of cosmetic materials, the public will feel that the Government has guaranteed their effectiveness and safety, and in the public mind the Government will share the blame for unavoidable accidents.

(6) Unlike drugs, cosmetics are not taken internally and harm from defective ingredients is seldom of a serious character. The danger to the public is not of sufficient magnitude to justify a further increase in Government control of private enterprise. Where a serious public danger exists, Government control is desirable; but the Government should not be permitted or required to step in with elaborate regulation to satisfy every complaint or fetish that comes to the attention of Congress. Where the motive of private industry for protecting the public is as great as that of a Government agency, Government interference is not needed.

(The list of products and ingredients submitted by Dr. Klarmann are in the files of the committee).

Mr. KLEINFELD. Dr. Klarmann, on the last page of your statement, item 4, you say:

> If the laboratories of private cosmetic companies were burdened with the red tape of pretesting requirements, their efficiency and effectiveness would be considerably reduced.

Suppose we had a law on cosmetics similar to the law which now exists in connection with new drugs; the law would require that before a new product is put on the market, the manufacturer must make tests to show that the product is safe and submit the results of his tests to the Food and Drug Administration. Do you call that red tape?

Dr. KLARMANN. I would not call this particular example red tape, Mr. Kleinfeld. I believe a distinction must be drawn between a new product which is constituted from well-known and customarily employed ingredients, incidentally ingredients which are used by dermatologists themselves, and a product which involves either a brand new type of chemical or a new application principle.

There is, as I have tried to bring out in the prepared statement, every reason to assume that the new product or the new principle will be pretested adequately before it reaches the market. This is shown by the fact that relatively speaking no evidence exists of any damage having resulted to consumers from the use of untested new products. By that I mean damage that could have been controlled rationally.

Now I am aware of the cases which the Food and Drug Administration has adduced in connection with the proposition which is now under discussion. That is the case, for example, of the shampoo, or the case of the nail-polish coat.

Mr. KLEINFELD. Let's discuss the shampoo, please.

Dr. KLARMANN. If I may comment on the shampoo. I would say this, Mr. Kleinfeld: Now that we have become aware of the existence of substances with potentially damaging action on the cornea, you may rest assured that every manufacturer of shampoo will certainly test his product for freedom from any irritation on the cornea. However, until this particular case has come to our attention, I doubt very

much—and I am not speaking as a dermatologist—I doubt very much that if we had submitted such a product to a dermatologist, it would have occurred to him to test it for eye irritation, simply because shampoos have been on the market for a great many years, and eye injury resulting from this type of product has never been reported before.

Now that we know of this possibility, we shall add the eye-irritation test as one of the must tests in pretesting cosmetics.

Mr. KLEINFELD. You say no dermatologist envisioned damage to the eye from the shampoo?

Dr. KLARMANN. I am not speaking as a dermatologist, but there are a great many shampoos on the market, and some of the more reputable companies must have had them tested by dermatologists. But I know of no published information on shampoo tests on eyes antedating the particular occurrence which is mentioned in the letter of Assistant Commissioner Harvey.

Mr. KLEINFELD. Isn't it a fact that some people were injured by the use of these shampoos?

Dr. KLARMANN. Yes; it is a fact.

Mr. KLEINFELD. Isn't it a fact that if the shampoos had been tested in the eyes of rabbits, injury would immediately have been seen?

Dr. KLARMANN. Yes; that is probably so. But this is due to the introduction of a new product in a shampoo which was not customary or known previously, in contrast to all the other shampoos of which there have been hosts on the market.

Mr. KLEINFELD. That is what we are talking about. You have a new product that you are putting on the hair. Is it unreasonable to assume that it may get into one's eyes?

Dr. KLARMANN. It is very reasonable to assume that.

Mr. KLEINFELD. Then, why——

Dr. KLARMANN. It was unexpected, however, to assume that the product, after having gotten into the eyes, would cause any permanent injury, something that wouldn't wash out with water.

Mr. KLEINFELD. How can you tell without testing?

Dr. KLARMANN. Precisely because of this: Up until then we didn't know about the possibility of such things. Now we know there are such things. Then we have to be very careful with any new materials entering into shampoo formulas, and will be in the future.

Mr. KLEINFELD. Isn't what you are saying, Doctor, that whenever an injury occurs, we then ought to change our procedures? Isn't that it?

Dr. KLARMANN. Beg pardon?

Mr. KLEINFELD. Aren't you saying that whenever any injury occurs, at that time we ought to make a change in our cosmetic preparations and formulation?

Dr. KLARMANN. We should take notice of that, and introduce such tests that will prevent injuries from occurring.

Mr. KLEINFELD. But meanwhile injuries have occurred; is that right?

Dr. KLARMANN. That is right.

Mr. KLEINFELD. Is the eye composed in part of mucous membrane?

Dr. KLARMANN. The eyelid has a mucous membrane.

Mr. KLEINFELD. As far back as December 1944, an article was printed in the Journal of Pharmacology and Experimental Therapeu-

tics, volume 82, No. 4, December 1944, entitled, "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes," by three gentlemen employed by the Food and Drug Administration.

Dr. KLARMANN. Dr. Draize and coworkers.

Mr. KLEINFELD. Drs. Draize, Geoffrey Woodard, and Calvery.

Dr. KLARMANN. That is right.

Mr. KLEINFELD. They say this, for example:

Irritation of mucous membranes is measured on the rabbit's eyes and penis—

They say later:

In the measure of injury to the eye, a modification of the scoring system of Friedenwald, Hughes, and Herrmann is used. Injuries to the cornea, conjunctival and palpebral mucosae, and the iris are scored separately. In testing the materials (liquids, solutions, and ointments) 0.1 millimeter is instilled in the conjunctival sac.

That is back in 1944.

Dr. KLARMANN. Yes, sir.

Mr. KLEINFELD. Doesn't that indicate that a careful person would in any event, where a product is to be applied in an area where there is mucous membrane, make rabbit tests?

Dr. KLARMANN. As far as I understand this paper, Mr. Kleinfeld, this is a method of testing the irritancy of various materials by using the eye as the test object. It is not a method anticipating the injurious quality of certain shampoos.

In other words, if a dermatologist, who is familiar with the customary procedure of patch testing had been given a shampoo for the determination of its irritant action, he might have tested it also on the scalp, in order to ascertain any irritant action on the scalp. I concede that if he had been particularly far-sighted he might have thought of the risk of the shampoo running into the eyes and causing injury. I will say that in most cases, he would not have thought of it. He would have said that if this product were not irritant under the conditions of its intended use, then it should receive his clearance.

What we are discussing here is the result of progress and development in the field of new materials entering into cosmetics. Now that we know that this particular contingency exists, every self-respecting manufacturer of shampoos will, of course, be particularly careful to have his product tested for eye irritancy.

The CHAIRMAN. Off the record.

(Discussion off the record.)

Mr. KLEINFELD. Doctor, a couple of days ago we had testimony here from a representative of the Colgate-Palmolive-Peet Co., who, in discussing the tests they had made on their Halo shampoo before putting it on the market, said in addition to other tests their studies consisted of determining the irritation of solutions of the material on the shaved skin of rabbits and in rabbits' eyes. The company was talking about its Halo shampoo?

Dr. KLARMANN. Yes.

Mr. KLEINFELD. The witness also testified that that type of testing was done many years ago. Apparently they do more comprehensive testing than your company. Is that correct?

Dr. KLARMANN. Well, they are a shampoo house, and they must have had a great deal of foresight in this respect.

Mr. KLEINFELD. They must have had foresight?

Dr. KLARMANN. A great deal more than many other companies.

Mr. KLEINFELD. But they did it before these recent injuries; isn't that correct?

Dr. KLARMANN. I don't know. If your records show that——

Mr. KLEINFELD. If they did, it means they contemplated such possibility of harm from the shampoo getting into the eyes?

Dr. KLARMANN. Not necessarily. As I pointed out before, Dr. Draize's tests are for determination of irritancy in general. His test is not primarily intended to show the injury to the eye. It is the other way around. The eye is used as the organ on which irritancy is determined, because it is a sensitive organ and the findings on the eye would apply with greater force to conditions found elsewhere.

Mr. KLEINFELD. That is quite a statement, Doctor, but it is a fact that this company, Colgate-Palmolive-Peet, testified that years ago, when they put out their product, their shampoo, they tested it in rabbits' eyes to find out what was going to happen.

Dr. KLARMANN. If that is what the statement says; yes, sir.

Mr. KLEINFELD. That is being rather careful, is it not?

Dr. KLARMANN. That is showing an interest in extending the testing to the widest possible area so that not only does one use the skin as the test medium, but also the eye. Not having talked with the gentlemen from Colgate's, I can't tell you with what purpose in mind they ran these tests.

Mr. KLEINFELD. Is it reasonable to say their purpose was to prevent harm from being done to the eye?

Dr. KLARMANN. I haven't the remotest idea.

The CHAIRMAN. Of course, that is obvious, is it not?

Dr. KLARMANN. No, sir; not from Dr. Draize's paper.

The CHAIRMAN. It is to me.

Mr. KLEINFELD. Are your products being submitted to the American Medical Association's committee on cosmetics for acceptance?

Dr. KLARMANN. No, sir. But we do have our formulas reviewed by dermatologists from time to time. And I am proud to say at no time did we have any occasion to modify anything because of dermatological objection.

Mr. KLEINFELD. Do you know the difference between the provisions in the present act with respect to new drugs and cosmetics?

Dr. KLARMANN. Yes; I am familiar with that.

Mr. KLEINFELD. The present law requires, and has required since 1938, that before you can put a new drug on the market, not any drug, but a new drug, you must first submit data as to its safety to the Food and Drug Administration?

Dr. KLARMANN. That is right.

Mr. KLEINFELD. That your new drug, under the conditions of use for which it is intended, will not hurt anybody; is that correct?

Dr. KLARMANN. That is correct.

Mr. KLEINFELD. That has been in existence since 1938?

Dr. KLARMANN. That is right.

Mr. KLEINFELD. Have you any evidence that the drug industry has suffered because of that requirement?

Dr. KLARMANN. Not to my knowledge.

Mr. KLEINFELD. Because of red tape that has been in existence?

Dr. KLARMANN. Not to my knowledge. I think it is a very good provision.

Mr. KLEINFELD. But you don't think the provision would be a good one with respect to new cosmetics?

Dr. KLARMANN. The reason I don't think so, Mr. Kleinfeld, is this: In the case of new drugs there was considerable evidence that such a thing was necessary. At the present time the need for an amendment, let's call it a new cosmetic amendment, is largely hypothetic.

Mr. KLEINFELD. Do you know what the need was with respect to new drugs? For years nothing happened at all, and then one product was used which killed 100 people—a sulfanilamide preparation.

Dr. KLARMANN. I don't recall the whole history, but I know from the number of seizures the Food and Drug Administration has been carrying out for a number of years, that a lot of products were mislabeled, adulterated, or filthy and that they were sold to the unsuspecting buyer, and so something had to be done to stop the traffic.

Mr. KLEINFELD. And you think that doesn't hold true with cosmetics?

Dr. KLARMANN. No, sir.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Mr. Horan?

Mr. HORAN. For my information, where does a cold cream, for instance, quit being a cosmetic and become a salve?

Dr. KLARMANN. Become a salve?

Mr. HORAN. Yes; or a medicine. How do you make that distinction?

Dr. KLARMANN. At the present time the distinction as to when a cosmetic becomes a drug depends somewhat on the claim. When you make a claim or offer evidence that this particular substance has a functional effect that is reaching below the skin, by producing, let us say, an antiseptic action or by producing a rubefacient effect by way of bringing blood to the surface, or things of that sort, then it becomes a drug. A cosmetic is something whose action is superficial. Some cosmetics are also drugs. For instance, an antiperspirant cream applied to stop perspiration is not only a cosmetic but also a drug, because it restricts the flow of perspiration.

Mr. HORAN. It is a rather fine distinction, is it not?

Dr. KLARMANN. It is a distinction in the Food, Drug, and Cosmetic Act.

Mr. HORAN. Shampoo, if you put a little medicine in it, might become a mange cure.

Dr. KLARMANN. That is true. If you put an antiseptic in a shampoo and claim control of bacterial contamination you make it a drug. If you make no such claim and recommend the product merely for cleansing, it is not a drug.

Mr. HORAN. Thank you.

The CHAIRMAN. That is all, thank you.

We will recess until 2 o'clock.

(Whereupon, at 12:40 p. m., a recess was taken until 2 p. m. of the same day.)

AFTERNOON SESSION

The CHAIRMAN. The committee will come to order.

Mr. KLEINFELD. Dr. Sharlit.

The CHAIRMAN. Your name and address, sir?

Dr. SHARLIT. Herman Sharlit, 32 East Sixty-fourth Street, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF HERMAN SHARLIT, M. D., NEW YORK, N. Y.

Mr. KLEINFELD. Doctor, where did you obtain your medical degree?

Dr. SHARLIT. Cornell University.

Mr. KLEINFELD. What year?

Dr. SHARLIT. 1917.

Mr. KLEINFELD. How long have you specialized in the field of dermatology?

Dr. SHARLIT. About 22 years.

Mr. KLEINFELD. You are a fellow of the American Medical Association?

Dr. SHARLIT. Yes.

Mr. KLEINFELD. And certified in the field of dermatology by the American Board of Dermatology and Syphilology?

Dr. SHARLIT. Yes.

Mr. KLEINFELD. You are a member of the American Dermatological Association?

Dr. SHARLIT. Yes.

Mr. KLEINFELD. And of the American Academy of Dermatology and Syphilology?

Dr. SHARLIT. Yes.

Mr. KLEINFELD. You are assistant professor——

Dr. SHARLIT. Associate professor.

Mr. KLEINFELD. Pardon me. Where?

Dr. SHARLIT. At the Postgraduate Medical School, New York University.

Mr. KLEINFELD. Have you contributed papers in the field of dermatology to the professional publications?

Dr. SHARLIT. Yes.

Mr. KLEINFELD. Are you a consultant to various cosmetic manufacturers?

Dr. SHARLIT. Only for one cosmetic manufacturer, but I do consulting work in the pharmaceutical industry, too.

Mr. KLEINFELD. For which cosmetic manufacturer do you do consulting work?

Dr. SHARLIT. Helena Rubinstein.

Mr. KLEINFELD. Will you read your statement, please?

Dr. SHARLIT. I imagine you refer to this letter I wrote you. Is that what you call a statement?

Mr. KLEINFELD. Whatever you wrote to us, call it what you will.

Dr. SHARLIT. Obviously no new product for application to skin should be generally marketed without adequate preliminary use tests to establish acceptable safety, be the product a drug or cosmetic. Although under present law there is no requirement that evidence of acceptable pretesting of new cosmetics be submitted for inspection and approval, my experience with the cosmetic industry would indicate that it has, on the whole, operated with a wholesome sense of its responsibility to the public in the preparation through testing of what might be reasonably considered a new cosmetic. I believe the record

proves this. As I review the few unfortunate experiences in recent years of the marketing of genuinely harmful cosmetics, I see in each instance circumstances that were unique and unusual—circumsances that could well lead to a failure of presumably acceptable pretesting to disclose or even suggest the ulitmate hazard revealed through mass use.

The distinction between acceptable pretesting and effective pretesting is real and goes to the heart of the problem of what should be accepted qualitatively and quantitatively as allowable untoward effects from cosmetic products. As referable to the commonest damage from cosmetics, a simple, banal dermatitis induced on an allergic basis—and, incidentally, the most frequent elements in cosmetics to induce them are the fragrancies—I hold the opinion that the industry is in possession of practices of pretesting adequate to discover products that could give a too high an incidence of allergic reactions. As to unanticipated types of damaging effect from cosmetic practice into which category I would place the eye damages from shampoos and nail base damage from base coats, ordinarily practiced pretesting could and did fail to disclose the hazard in time. In the light of the disclosure of these latter types of damage, pretesting practices should be modified—and already have been with respect to shampoos—with respect to some products.

Much good would flow from the cooperation of the industry with Food and Drug Administration in a complete study of all the aspects of the pretesting problem as applicable to all cosmetics.

The CHAIRMAN. Mr. Kleinfeld?

Mr. KLEINFELD. Doctor, in your statement you say that the eye damage from the shampoos was an unanticipated type of damage. Now why do you say that?

Dr. SHARLIT. Oh, of course, a shampoo isn't made to be thrown in the eye. It is true that incidentally, no matter what effort you make to avoid getting some shampoo mixture in your eye—I have been in this industry for many, many years and have had occasion to concoct shampoos and to have them tested. I would never think of deliberately throwing these things into the eye to see if some unexpected damage would accrue from that. It hasn't been a practice. That is why this wasn't discovered.

Mr. KLEINFELD. Well, we had testimony from Colgate that they had done just that sort of testing many years ago with their shampoos. Now, they must have thought that it was possible that damage would result to one's eye by reason of the shampoo.

Dr. SHARLIT. Let me tell you that the point at which the testing has to be done, whether it is with respect to an ingredient or with respect to a finished product, is very important in directing the psychology of the examiner and the concocter. The fellow who makes the ingredient, these synthetic detergents, and is looking for a market must be very keen as to what his possibilities are, where the market would be and where it wouldn't be; and he would have in mind testing the ingredient for all possible damage to all areas exposed to that ingredient no matter how used. But if an ingredient such as that detergent is brought to somebody that is going to make a shampoo and is recommended as a detergent, as a wetting agent, as a surface tension reducer for this mixture, the man who uses it probably gets the impression it is safe to use and he is using it for the specific

purposes for which it has been recommended—its physical properties. And he overlooks to make that test.

I am just saying this: That if I was unfortunate enough to have these quaternary ammoniums thrown at me for inclusion in a shampoo, I might have been the culprit who overlooked it, and I am willing to be liberal enough to say somebody else overlooked it, too.

Mr. KLEINFELD. Well, somebody else overlooked it; is that right?

Dr. SHARLIT. Yes. It wasn't a usual practice.

Mr. KLEINFELD. Now it is, isn't it?

Dr. SHARLIT. It had better be. I don't know whether it is a usual practice. I have never seen any of the cases. I spoke to men in Washington who went down and saw the case and told me about it, and I don't want to ever see a case I am responsible for.

Mr. KLEINFELD. Would you recommend that something used for a bubble bath should be tested in rabbits' eyes before its use?

Dr. SHARLIT. Pardon me? Used as what?

Mr. KLEINFELD. Should a substance to be used in a bubble bath preparation first be tested in a rabbit's eye?

Dr. SHARLIT. Obviously, that would come into the same category. If anything is going to get in your eye, you want to make sure that the eye is safe from an incidential inclusion of the material in the eye.

Of course, we all know that soap in the eye irritates for a few minutes, makes it red for 2 or 3 days—perfectly harmless. But I understand that the effects of these specific detergents were terrific. In other words, this was a brand-new experience, and that is how we learn, unfortunately. Some of these experiences are sad, but that is the way we learn.

Mr. KLEINFELD. You mean we learn because of damage which occurs; is that right?

Dr. SHARLIT. Certainly we learn what happened and what can happen.

Mr. KLEINFELD. For example, some time ago Rohm and Haas put out some advertising literature. Part of it was their report on the investigation of the corneal irritation characteristics of Triton X–100, which was to be used for bubble bath purposes.

Dr. SHARLIT. Yes.

Mr. KLEINFELD. Quite some time ago. And Rohm and Haas advised people who bought this preparation as follows:

> In order to evaluate the practical significance of these data we related the lowest indicated irritating concentrations to those used for bubble-bath purposes. The usual practice is to employ a total of two grams of Triton X–100 for producing bubbles in the bath. Assuming that the average bath consumes about 20 gallons of water, the use concentration of the triton would be about 1:38,000, which allows a 38:1 safety margin before any irritation is encountered. Even when children's baths are considered, the minimum volume of about 5 gallons of water would give a use concentration for the triton of about 1:9500, which allows almost a 10:1 safety margin over the irritating concentration.

So apparently Rohm and Haas, as well as Colgate, envisioned the possibility of substances put in shampoos or bubble baths getting into people's eyes.

Dr. SHARLIT. I didn't mean to imply it is the first time I ever heard of a shampoo getting in the eye. I got it in my eye plenty of times. But it is the first experience where any ingredient of a mixture such as that had the possibility that eventually proved to be shown for

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that particular detergent which was used in the products concerning which we are talking.

Mr. KLEINFELD. But if the manufacturer had taken the trouble, because it was using a combination not theretofore used, to make a test, that injury would not have occurred?

Dr. SHARLIT. In other words, if he didn't offer it for sale for that use, nobody would have had it for use and nobody would have been damaged, obviously.

At this point, I might say I am quite in favor of setting up a certified list for synthetic detergents just as we have for colors. Why not? Let the fellow who makes it go through all the effort to determine whether he is allowed to sell it for certain purposes.

Mr. KLEINFELD. You are not limiting yourself to synthetic detergents, are you?

Dr. SHARLIT. I think soaps are pretty safe. I wouldn't want anybody to bother about soaps after 2,000 years. You know what they can do.

Mr. KLEINFELD. How about any cosmetic where you use a combination of ingredients not theretofore used?

Dr. SHARLIT. A combination of ingredients known but mixed in this one unusual way?

Mr. KLEINFELD. Yes.

Dr. SHARLIT. That leaves me pretty cold as being of importance. Because in the first place we know what the type of damage is in 99.9 percent of the cases. It is a simple dermatitis and it is on an allergic basis. And if we get into the question of determining just what incidence of allergic response to accept and what we can't accept, we are getting into more than medicine, we are getting into philosophy. And it has been my experience that the consumer decides what is an acceptable degree of damage, neither the doctor nor the law. And that has happened in the cosmetic industry on several occasions. If you want me to, I will explain what I mean by that and what has happened.

Mr. KLEINFELD. You mean that if enough damage occurs, people stop buying the product.

Dr. SHARLIT. No. I mean that if enough people like a product, they are not concerned with who else is damaged. They want it and they go out and get it. And the law finally says, "All right, all you people who want it, for the poor people who can't use it, we will put something on the label to protect them—if they read labels—but we are going to make it available."

Isn't that true of para dyes in hair? Twenty years ago I appeared before the commissioner of the City of New York when the whole group of beauty operators went up to protest the sanitation code of the city, the prohibition in the code against the use of para dyes on hair. They said they were losing all their customers, the customers were all going up to Yonkers to have their hair dyed. The few of the operators who were willing to bootleg the dye into New York were having all the business, and the others who wanted to abide by the sanitary code were losing the business.

What was the outcome? They decided to permit them as operators, so-called skilled workers, to use para dyes in hair with regulations about signs in the booths—patch testing, watching out for abrasions of the scalp before it was used. But the point was they allowed the use of para dyes in hair when applied by an expert operator.

Now, within the last year what has happened? Now the law is allowing para dyes to be sold, to be taken home where inexpert amaturs are now using it in the hair. Why was all this changed? Because the consumer said, "I want it. Don't tell me it does damage. It didn't do me any damage. I want it." And they got it.

Mr. KLEINFELD. Where did you get the impression that the consumer coming in and making that demand caused that change?

Dr. SHARLIT. I thought I was telling you a story.

Mr. KLEINFELD. It is a story, and I am trying to find out the source.

Dr. SHARLIT. The operators were losing customers because they were going where they could get a certain ingredient used on their scalp. They left the city of New York to get it, and the operators wanted those customers back. I think that goes right back to the consumer.

Mr. KLEINFELD. You mean the change in the law was caused by that sort of consumer demand?

Dr. SHARLIT. Para dyes are dangerous. There was a time when you could get a fairly good hair dye with vegetable dyes. There were operators who learned how to use them and make a fairly good job. But the para dyes do a better job, and they are easier to manipulate, and you don't have to be so expert.

Now, the city of New York wouldn't allow these para dyes to be used in the city of New York, but the city of Yonkers did, and the beauty operators in New York were losing their business because women noticed that other women were getting a better job done and went after it. The fact that New York wouldn't allow it to be used didn't mean anything to them.

There was a reason. They never made inquiries. They didn't care, they wanted to take the risk.

Mr. KLEINFELD. Maybe the answer is to have Yonkers pass similar regulations.

Let me get your point, Doctor. Are you saying that if a product is dangerous and people want it, they ought to be able to get it?

Dr. SHARLIT. I am saying that ultimately in the last analysis the people decide what ultimate risks should be for the public. Everyone decides for himself.

Mr. KLEINFELD. Let me go into it a little further. Suppose a lot of people want sleeping pills. Under the law they are not supposed to be able to get sleeping pills without the prescription of a doctor.

Dr. SHARLIT. Yes.

Mr. KLEINFELD. There are a lot of people who want sleeping pills in New York City, Yonkers, or some place else. Are you saying because they want it they ought to be able to get it?

Dr. SHARLIT. No. The analogy isn't perfect, you know.

Mr. KLEINFELD. Pardon?

Dr. SHARLIT. The analogy isn't perfect, you know.

Mr. KLEINFELD. Why isn't it?

Dr. SHARLIT. For the simple reason that there are other methods of getting it. The law doesn't say you can't get sleeping pills. It regulates the manner in which you can get it. You make a prohibition against ever getting a sleeping pill through a doctor and elsewhere, and then you come and tell me what happens.

Mr. KLEINFELD. Aren't there some things you can't get under any circumstances in this country, like heroin?

Dr. SHARLIT. You can get that under the proper circumstances.

Mr. KLEINFELD. It is pretty difficult, though, isn't it?

Dr. SHARLIT. I probably haven't made my point clear. Have I?

If you are comparing a method for getting heroin with a method for getting a cosmetic which has a certain incidence of damage and therefore should be prescribed for everybody so that the few who are damaged might not be damaged at all, I have not made myself clear. In other words, there is no longer the philosophy of the greatest good for the greatest number. It is going to be the greatest good for the idiosyncratic few.

Mr. KLEINFELD. Let's assume, Doctor, that Congress determines that the type of dyes to which you have been referring contains such elements of possible danger for some people that the Congress is not going to permit that dye to be used any longer.

Dr. SHARLIT. What would happen?

Mr. KLEINFELD. What would happen?

Dr. SHARLIT. Bootleg it. Bootleg it. That is what was done then—they were bootlegging it. You don't just bootleg liquor, you bootleg whatever you want. If you want it bad enough, and there is a way to get it, you bootleg it. If a cosmetic, you bootleg that.

Mr. KLEINFELD. You mean the crying demand for that type of dye is so vast it would be bootlegged?

Dr. SHARLIT. Obviously, either that or those who take care of the laws have been very deficient in their duties, because we have gone from prohibition in the city of New York to a beauty parlor expert operator, and now anybody can buy in the store and you have national distribution of para dyes. They have never been made safer. Don't think there is any implication in all these changes that the product is any safer; it is not. They are just as dangerous, to the extent you want to call it dangerous, as they ever were.

However, if you read the label and the cautions contained thereon aren't enough to scare anybody away from the use of the product, the only thing left to do would be to put the address of an undertaker on one side so that all eventualities might be properly covered on the label. That doesn't keep the consumer from buying it. The law does everything to protect them, but they want it and they get it.

Mr. KLEINFELD. Then your point is if people want it badly enough, even though dangerous, they ought to be able to get it?

Dr. SHARLIT. I thought we were talking about prohibitions because of danger, and I was trying to point out that the consumer decides what can or can't be or should not be, if you want to put it that way, prohibited.

Mr. KLEINFELD. I thought it was the Congress that did it and made anybody that violates the law subject to penalty.

Are you in agreement with the very first sentence? You say:

> Obviously no new product for application to skin should be generally marketed without adequate preliminary use tests to establish acceptable safety.

Is that your position?

Dr. SHARLIT. Certainly.

Mr. KLEINFELD. Who should be the judge of whether the tests are adequate?

Dr. SHARLIT. The one who makes it.

Mr. KLEINFELD. If he thinks it safe, he ought to be permitted to put it out?

Dr. SHARLIT. He assumes the responsibility.

The CHAIRMAN. Suppose he is irresponsible?

Dr. SHARLIT. Well, the common law gets him, among other things.

The CHAIRMAN. Eventually. In the meanwhile, what happens?

Dr. SHARLIT. Well, I assume there aren't any rascals running businesses of any kind in America. There are a few. But we can't go ahead on that basis, Mr. Delaney. At least, I don't feel that way. Certainly there are rascals, but if everything was looked at from the point of view of how the rascals can break into this and what damage they can do, I would have to change my whole philosophy about a lot of things, not only cosmetics, but everything.

Looking at your statistics, when a company can sell tens of millions of units per year and get a hundred or so complaints, a good proportion of which are phony, is there any indication that that kind of practice is overlooking something for the public benefit? I don't think so; I don't see it.

You ask the insurance companies their experience. You go right back to the source where it hurts most, the pocketbook, and find out what damage cosmetics are doing the public.

Mr. KLEINFELD. Doctor, let's go back a little bit, before the present law was passed in 1938. Very shortly before that there was a preparation sold for beautifying the eyelashes which caused permanent blindness to a number of women. Would you be willing to permit the ordinary manufacturer to decide whether he wanted to put out such a product or not?

Dr. SHARLIT. Mr. Kleinfield, I was the Government expert in that case.

Mr. KLEINFELD. Yes?

Dr. SHARLIT. The Government seized the product, as they should. And the owner went before a jury to bail it out.

I think I was on the witness stand 7½ hours; 7½ hours trying to tell this jury that this ingredient was dangerous and not essential to the very product that it was contained in. And this jury of our peers decided that they didn't know what the right answer was and they just hung the jury.

And I am perfectly willing to make a few statements because this is the first chance I got to talk about juries. I never serve on them.

We went around among these fellows afterward to find out how they were thinking, and they were pro or against Roosevelt. That is, how they made a decision as to whether pyrogallic acid should be used, they were for or against Roosevelt.

You asked me whether I was in favor of selling pyrogallic acid, and the answer is "No." I testified so.

Mr. KLEINFELD. Let me ask you for a direct answer. Would you be in favor of allowing the manufacturer to decide, on his own responsibility, whether he wanted to use a product for the eye containing that substance?

Dr. SHARLIT. Yes, until such time as the facts proved he was wrong.

Mr. KLEINFELD. If in the meantime some woman is blinded, that is unfortunate; is that right?

Dr. SHARLIT. Yes; that is unfortunate.

Mr. KLEINFELD. I have no other questions.

The CHAIRMAN. Dr. Hedrick?

Dr. SHARLIT. I just want to make another remark, because you left it on a very sad note. It is unfortunate when, for example, one crosses the street and gets bumped off by an automobile.

Mr. KLEINFELD. That is right.

Dr. SHARLIT. That is one of the highest causes of death in America—accidents. No one wants to put governors on motors and they run them down.

Mr. KLEINFELD. Are there no requirements for testing drivers before issuing licenses, and in some States for testing cars?

Dr. SHARLIT. Certainly there are. Given all the rules and regulations that you want and a few more than you want still doesn't slow the automobile down with a controller.

Mr. KLEINFELD. Does that mean you want to lift all controls from automobiles?

Dr. SHARLIT. If you gave me a job of saving lives from automobile accidents, there are a lot of things I would do the automobile people wouldn't like, such as slowing cars down to 30 miles an hour.

Mr. KLEINFELD. You would impose some restrictions, would you not?

Dr. SHARLIT. Yes.

Mr. KLEINFELD. I have no more questions.

Dr. HEDRICK. Are you familiar with the present Food, Drug, and Cosmetic law?

Dr. SHARLIT. Since 1938 you mean?

Dr. HEDRICK. Yes.

Dr. SHARLIT. Yes.

Dr. HEDRICK. Do you think that law should be improved today or is it adequate to take care of the situation?

Dr. SHARLIT. Are you referring to the cosmetic section?

Dr. HEDRICK. Yes.

Dr. SHARLIT. I can only speak from my own experience. I don't suppose anybody can speak from anybody else's. I have never discussed this with others to know how they feel about it.

Professionally, I would say the law is adequate, but I would like to see the manufacturer of ingredients, particularly synthetic resins and synthetic detergents, do a little more work with the things they try to sell to the industry. I wouldn't be adverse to seeing that the Food and Drug Administration was charged with the duty of getting up a satisfactory list of such products that they would consider certified for use in cosmetics, and at the same time they could see what would be certified for use in washing.

You can see a lot of skin damage, not from things put on the skin deliberately, but from soaking your hands in a lot of detergents that are used for cleaning lingerie and what have you. So they might as well cover that while they are at it.

Dr. HEDRICK. What type of law should we have to control the new drugs coming on the market—some that haven't been tested and that we know very little about?

Dr. SHARLIT. If you assume that it is a practice—taking somebody's advice, to probably mix things together in a jar and call it a cosmetic and put it on the market, and if the one who is consulted as to the mixing is a fellow who says, "You need no testing," and therefore is one who is assuming his responsibility in an outrageous sort of way, then you can legislate against these outrages if such practices are indulged

in. I don't know where they occur or when they occur—just mixing together and tomorrow you got it on the market. I really don't think that happens.

Dr. HEDRICK. Don't you think it is a dangerous thing to let the public be exposed to new drugs and chemicals when nobody knows anything about what they will do and what their action is?

Dr. SHARLIT. You are right, but is that a fact?

Dr. HEDRICK. I think it is. I think it is perfectly true. There are over 800 chemicals on the market, and no organization can go into 800 of those things and determine what they can do.

Dr. SHARLIT. Of course, you are including there drugs, and the Drug Act asks for tests on new drug applications. It is only the cosmetic business that is free and clear and fancy-free at the moment, not the drugs. And the cosmetic manufacturers are selling some materials that are in the drug category, and they have to make new drug applications for the product even though it is a cosmetic as it is marketed.

Dr. HEDRICK. That is all.

The CHAIRMAN. Mr. Horan?

Mr. HORAN. No questions.

The CHAIRMAN. That is all, Doctor.

I think, Doctor, you are interested primarily in cosmetics. This committee is interested in all chemicals, the use of chemical additives and their effect on human health—insecticides, pesticides, fungicides, and even chemical fertilizers.

Recently there was an amendment made to this resolution to include cosmetics, and this particular hearing deals more with cosmetics than any of the other phases of the investigation. So I can understand why you have cosmetics in mind.

Dr. SHARLIT. Well, the original telegram of invitation I got referred to cosmetics.

The CHAIRMAN. Yes. I say we are concentrating more or less on cosmetics because it is of recent origin.

Dr. SHARLIT. I never felt you can pass laws to make people honest. You can only pass laws to punish them, but you can't make them honest.

The CHAIRMAN. We don't know what we are going to do. We are seeking advice before we take the time of the Congress in order to make a reasonable presentation of the facts, and then they will decide for themselves what they want to do, if anything. I don't know.

You can realize that 435 men in the House cannot go into this phase as much as this committee has gone into it. We must make some sort of recommendations based upon the testimony of those witnesses who have appeared before us. We will try to get our views coordinated so we can agree on something. Just as you said the jury had difficulty, unquestionably there will be differences of opinion among the members of this select committee.

Dr. SHARLIT. May I make a comment, please?

The CHAIRMAN. Surely.

Dr. SHARLIT. I have learned long ago that when somebody is elected to be an expert and takes a seat in public to speak as an expert, and he begins to speak ex cathedra there are three words he can't get to come out of his mouth in succession, and those three words are "I don't know." He knows the answer to everything.

The CHAIRMAN. Wait a second. I don't want to interrupt you there, but on numerous occasions I think whenever any members of this committee have been called upon by a group to talk on this subject—and the occasions have been numerous—I think the words that are used most are "We just don't know."

Dr. SHARLIT. Well, I would want to follow that story up with a suspicion that a committee investigating a situation finds it hard to come back with an answer, "We don't think that a new law or modification of a law is required." That is just as hard to do sometimes.

The CHAIRMAN. Well, I don't know whether it is or not. I haven't any idea. I wouldn't even hazard a guess one way or the other on what this committee will do. However, I want you to know that we are devoting a great deal of time to this in an effort to get the right answers.

Dr. SHARLIT. I appreciate that.

The CHAIRMAN. Whether we get them or not, or what report we make, is something else.

Dr. SHARLIT. Like a good citizen, I will abide by any law you give us or you don't give us.

The CHAIRMAN. Thank you, Doctor.

Dr. SHARLIT. Thank you very much.

The CHAIRMAN. The next witness.

Mr. KLEINFELD. Dr. Louis Pyenson, entomologist.

The CHAIRMAN. Your name and address.

Dr. PYENSON. Louis Pyenson, Oak Street, Farmingdale, Long Island.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF LOUIS PYENSON, PH. D., ENTOMOLOGIST, LONG ISLAND AGRICULTURAL AND TECHNICAL INSTITUTE, FARMINGDALE, LONG ISLAND, N. Y.

Mr. KLEINFELD. Dr. Pyenson, your statement sets forth your biographical data?

Dr. PYENSON. Yes.

Mr. KLEINFELD. Please read your statement.

Dr. PYENSON. To indicate my qualification for presenting my views on the use of pesticides on food crops, I am first giving a summary of my educational and professional background.

I have a B. S. degree from the University of Massachusetts; a M. S. degree from Rutgers University; and a Ph. D. degree from Cornell University (1935). My major work at these institutions was mainly in economic entomology and plant physiology. After receiving my Ph. D. degree I spent 2 years in Brazil as head of the entomology section of an agricultural experiment station, and carried on research on the crop pests of the region and their control. Since 1938 I have been employed at the Long Island Agricultural and Technical Institute as an instructor in plant protection. A considerable part of my duties also consist of extension services in the field of plant protection.

I am the author of numerous scientific and popular articles on pests and their control, and of two books: Pest Control in the Home Gar-

den, 1944 (Macmillan Co.); and Elements of Plant Protection, 1951 (John Wiley & Sons).

I have read over much of the testimony of the hearings and agree with those that believe there is need for added legislation to protect the public and that the public is not adequately safeguarded under the existing legislation. I must state, however, that I have no sympathy with the "organic gardening cult" or the few pseudo-scientists that have been making headlines with unsubstantiated statements and theories that the increase of some of our fatal diseases is due to the use of some of our new pesticides.

Some of the new pesticides have appeared on the market with insufficient knowledge of their acute and cumulative effects on man and animals. Some of the information about acute and cumulative toxicity of the new organics beginning with DDT was forthcoming only after they appeared on the market and were being used by farmers and growers. A case in point was the use of DDT in dairy barns where its use was finally stopped when experiments showed that the milk in such treated barns contained small amounts of DDT and that this would produce cumulative effects on those consuming the milk over a period of time. I feel that all possible health and safety angles should be thoroughly investigated before a product is put on the market, and then its limitations should be clearly stated and its use, if necessary, limited to experienced or qualified personnel.

I am in favor of adding a law, comparable to the new drug section law, to the food chapter of the Federal Food, Drug, and Cosmetic Act. However, the position taken by the Commissioner of Foods and Drugs in his recommendations is too strong and if carried out to the letter would result in eliminating the use of many of our very valuable pesticides. I feel that only those chemicals should be sold freely to the public whose safety is not in question both on an acute or longtime basis when used and timed as recommended on the labeling. The underlined part of the statement would throw considerable responsibility on the growers where much of the responsibility has been and will have to be placed anyway, if production and quality are to be maintained.

I avoid the use of phosphate insecticides here at the institute as I think them much too dangerous for inexperienced students to handle even under supervision; yet anyone can go into a store and purchase them at present.

I suggest that the sale of the more highly dangerous pesticides be set up under a prescription system and their sale limited to personnel experienced or trained in their use, much like the purchase of poisonous drugs is limited by prescription in drug stores. This type of setup should not involve the formation of new Government agencies as country agricultural agents and/or other agricultural extension personnel such as extension entomologists and plant pathologists could be empowered to issue a prescription according to need to growers that have been instructed in the dangers involved and in the correct use of pesticide. These prescriptions would be accepted at horticultural supply stores. The proprietors would be forbidden by law to sell the designated highly poisonous pesticides to anyone other than bearers of prescriptions. If at any time growers have been found to be lax in the safe use of the pesticides, the use of the prescription could

be revoked. This seems to me to be a simple method to limit the sale of highly dangerous pesticides and safeguard the public.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. I just have one question, Doctor. You say you avoid the use of phosphate insecticides. What are these insecticides?

Dr. PYENSON. I was thinking of parathion, TEPP, and there is a new systemic one—Systox. Well, there are a few more. EPN is another one. There are several others that have a phosphate base to them.

Mr. KLEINFELD. The principal one is parathion?

Dr. PYENSON. That is one of the most outstanding ones; yes.

Mr. KLEINFELD. What has been your experience with the more or less new systemic insecticides?

Dr. PYENSON. Well, I haven't had any experience other than I have used one once. Our cabbages were heavily infested with aphids, and there wasn't anything else that could be used that would do the job we wished to have done. We got some of the Systox and applied it on the cabbages, and it did the job. That was at least a month and a half before the cabbage was to be used, so it was considered safe.

Mr. KLEINFELD. How do these systemic insecticides work?

Dr. PYENSON. They are absorbed either through the roots or through the foliage, depending on how they are applied. Then the toxic material is translocated to the foliage. Where the insects that suck the sap from the foliage get in their system and are killed.

Mr. KLEINFELD. Generally speaking, how will the food processor or canner be able to make tests on products on which these systemic insecticides have been used as far as residue is concerned?

Dr. PYENSON. Well, they will have to test for the actual chemical, but I understand after the chemical gets in the plant it sometimes changes its composition, and it might be difficult to find how much of the chemical was there in some other form.

Mr. KLEINFELD. That presents a fairly serious problem then, does it not, from the viewpoint of both the public and the food canner?

Dr. PYENSON. It does.

Mr. KLEINFELD. I have nothing further.

Dr. HEDRICK. Do you think there should be a restriction on the sale of DDT to the public?

Dr. PYENSON. No; I think DDT is fairly safe as far as insecticides go, except that it should not be used too close to the harvesting period of any edible crop. I think DDT is one of the safer insecticides.

Dr. HEDRICK. I do not think that is true of the vast majority of witnesses we have had before this committee. Most of them say it is a very dangerous chemical and should be watched very carefully.

Dr. PYENSON. I haven't hesitated in using it at all at the institute. I use it right along. The students use it right along. But I do hesitate to use the phosphate compounds, which I think are much more highly dangerous.

DDT, from the standpoint that it has chronic toxicity and a small amount of residue may cause eventual harm, is dangerous, but I think if it is used correctly that danger is eliminated.

Dr. HEDRICK. Have you heard that the present day virus may be caused by DDT?

Dr. PYENSON. Yes; but as I indicated in my remarks in my statement, I think that the doctor is more or less of a sensation hunter or sensationalist.

Dr. HEDRICK. In other words, you don't believe that?

Dr. PYENSON. No; because it hasn't been proven scientifically. He based his facts on clinical cases, and he did not actually run a test to show whether DDT will produce the effects that he said it did in those people. So unless he actually runs a test, he doesn't know whether it will or not produce the effects, and he is going just by what happened. And when you go by just what happened, you can be misled very easily. In many cases, it could be pure coincidence as far as the symptoms were concerned that the people were exposed to DDT.

Dr. HEDRICK. That is all.

The CHAIRMAN. Mr. Horan?

Mr. HORAN. No questions.

The CHAIRMAN. That is all, Doctor. Thank you.

Mr. KLEINFELD. Mr. Herrmann.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF CHARLES A. HERRMANN, CHIEF, NEW YORK DISTRICT, UNITED STATES FOOD AND DRUG ADMINISTRATION, NEW YORK, N. Y.

Mr. KLEINFELD. Mr. Herrmann, you are chief of the New York district of the Food and Drug Administration?

Mr. HERRMANN. Yes, sir.

Mr. KLEINFELD. How long have you been associated with the Food and Drug Administration?

Mr. HERRMANN. Thirty years.

Mr. KLEINFELD. And as chief of the New York district, what are your duties?

Mr. HERRMANN. I am responsible for the enforcement of the Food, Drug and Cosmetic Act in this New York district area, which comprises the eastern half of New York State, northern half of New Jersey, and western half of Connecticut.

Mr. KLEINFELD. Please read your statement.

Mr. HERRMANN. Investigation and Findings of the Food and Drug Administration Leading to Recent Seizures of Chickens Treated with Diethylstilbestrol.

The practice of treating poultry with the synthetic chemical diethylstilbestrol began in 1947 and has grown rapidly. Millions of birds are now treated annually. It is estimated that over 30 million pellets were marketed in 1950. The process consists of implanting pellets or paste containing diethylstilbestrol by means of an injector in the loose skin close to the head. Injection of young cockerels at this point is supposed to yield the maximum effect and also insure that any pellet residue remaining unabsorbed at time of slaughter will be discarded with the head. The purpose of use is to produce a temporary caponizing effect in male birds so that they will be tenderized, develop improved flavor and produce more body fat and increased weight.

The employment of this method in the poultry industry following new drug procedure under the Food, Drug, and Cosmetic Act was predicated upon a satisfactory showing of safety, that is, that when used according to directions there would be no deleterious or adverse effect upon the consumer of the edible portions of the birds so treated. Last spring we undertook a survey to determine whether these conclusions were still sound or whether perhaps the whole problem ought to be re-evaluated. There was a lot of publicity at that time growing out of the hearings of this committee relative to chemicals in foods and the time seemed opportune to check up and see how the thing was working in actual practice.

The first thing we did was to examine some of the lots of poultry coming into the New York wholesale market. The two inspectors specializing in poultry at New York district looked at nine lots of treated poultry and found that approximately 70 percent of the birds contained residual pellets of diethylstilbestrol. Laboratory examination of three samples showed two to four milligrams of diethylstilbestrol in the unabsorbed residues. In at least 50 percent of the cases, the site of implantation was found to be from 1 to 1½ inches below the base point of the skull and there was a significant number of birds in which the remainder of the pellet was two or more inches below the point where it should have been implanted.

The inspectors then made incognito visits to five butcher shops and made five purchases, involving 10 birds. The heads and portions of the upper neck were removed from the birds by the butcher following the customary trade practice of dressing the birds at the time of sale. Nine of these showed no pellets remaining but one bird eviscerated by the butcher for home consumption yielded a residual pellet of diethylstilbestrol estimated at three milligrams.

This preliminary investigation indicated that poultry raisers were not adhering closely to the instructions in implanting the pellets and that in the normal course of dressing the birds at the butcher shop, consumers might be getting fully dressed birds containing appreciable diethylstilbestrol residues.

With this background, plans were developed to secure official samples of shipments that had moved in interstate commerce with a view to seizure if findings confirmed preliminary conclusions. On Monday, July 2, the first lots of diethylstilbestrol-treated birds were examined. Six separate lots comprising altogether some 369 crates were found to have appreciable residues from improperly made implantations. On the following morning, July 3, the survey was continued and although the search was begun at 4 a. m. and covered the entire known receiving market in the Greater New York area, not a single lot of diethylstilbestrol-implanted poultry marked to show they had been treated could be located. Apparently the word had gone out from the dealers in the local wholesale market and shipments were being withheld.

Immediately following the preliminary investigation at the New York wholesale market, the Food and Drug Administration also conducted investigations in nine other large poultry markets, but no diethylstilbestrol-treated birds were found. The market survey in the New York area was continued periodically until early September but the shippers had already been thoroughly advised concerning our activities and had taken measures to forestall our action because we

found several lots of poultry marked "Roasters"—the designation for roasting chickens which have not been chemically treated—which actually consisted of treated birds.

Altogether, we took seizure action agalnst 13 lots, aggregating 792 crates, or 60,000 pounds, with a wholesale value of approximately $25,000. The seized lots originated with seven different shippers respectively in Maine, New Hampshire, Connecticut, North Carolina, and Pennsylvania.

The routine followed in the collection of these official samples preliminary to seizure was first to make visual examination of one or two birds from each of six or eight crates. Where pellets were found present in these birds, a record was made of the site of implanation in relation to the back of the head where the injection should have been made and two or more of the residual pellets were taken for chemical examination in the laboratory. In each case the residual material was definitely identified as diethylstibestrol and the quantitative findings in the respective birds ranged all the way from three or four milligrams to a high of 24.3 milligrams.

Following seizure, claims were filed in each instance, and in condemnation decrees protected by adequate bond, salvage was permitted under the immediate supervision of an inspector of the Food and Drug Administration. The salvage consisted of the removal of the entire necks at the shoulders and further evisceration of each bird. The necks so removed were denatured with Lysol and moved to a fat rendering plant. On completion of this process the edible portion of the bird was released for the market.

Incidental to the supervision of salvage, our inspectors made some counts on the removed necks that are of interest. In the salvage of three consolidated lots examination of approximately 200 birds revealed about 95 percent as containing pellets estimated to average between 5 and 7 milligrams. Over 50 percent of these were 1 inch or more below the base of the skull. In another lot, approximately 300 birds were examined. In that case only about 50 percent showed evidence of having been implanted at all, but of these 50 percent, three-quarters were an inch or more below the skull and the residues were estimated as averaging 5 to 6 milligrams.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Mr. Herrmann, you are here merely to inform the committee of the facts surrounding these seizures of diethylstilbestrol-treated poultry; is that not right?

Mr. HERRMANN. That is right, our market findings in this area.

Mr. KLEINFELD. Your findings as to the seizures; is that correct? In other words, as to what actually occurred when the chickens were seized?

Mr. HERRMANN. Well, of course, the preliminary part of the statement is concerned with our discovery that the directions for use under which the new drug applications became effective were not being followed and required regulatory action in order to provide consumer protection and get those chickens off the market.

Mr. KLEINFELD. You say, on page 2 of your statement, that your two inspectors specializing in poultry in the New York district looked

at nine lots of treated poultry and found that approximately 70 percent of the birds contained residual pellets of diethylstilbestrol.

What does that mean?

Mr. HERRMANN. That means that the pellet injected had not been entirely absorbed by the animal before slaughter.

Mr. KLEINFELD. Under the new drug application are they supposed to have been fully absorbed?

Mr. HERRMANN. I don't know exactly the terms of the new drug applications, but even if they were not entirely absorbed, the directions for implanting way up in the head, in that portion of the head which would normally be removed and discarded by the butcher in dressing the bird, would have taken care of any unabsorbed residues if the pellets had been properly implanted.

Mr. KLEINFELD. And can we conclude, from what you said in your statement, that the directions pursuant to which the new drug application was approved by Food and Drug were not being followed?

Mr. HERRMANN. That is true.

Mr. KLEINFELD. And not being followed in a large majority of instances?

Mr. HERRMANN. I don't have any figures on the proportion of cases in which they were not being followed, but from the total number of lots found in violation and the relative ease with which they were located in the New York area, there was a general laxity in following directions of implantation.

Mr. KLEINFELD. I may have asked you this—as far as you know, these new drug applications were approved on the basis of specific directions for use, including method of implantation and period of time beyond implantation before the sale of the poultry?

Mr. HERMANN. That is right.

Mr. KLEINFELD. And is the Food and Drug Administration now reexamining the situation because of the widely prevalent failure to observe those precautions?

Mr. HERRMANN. I think the matter is under consideration and reevaluation, whether perhaps those applications should be withdrawn.

Mr. KLEINFELD. That is all I have.

The CHAIRMAN. Dr. Hedrick.

Dr. HEDRICK. Doctor, have you made any inspection of the use of these pellets in sheep, hogs, beef cattle, and so on?

Mr. HERRMANN. No, we haven't, because I don't believe there are any new drug applications in effect covering those animals. None to my knowledge.

Dr. HEDRICK. You mean not being used in this section?

Mr. HERRMANN. Not to my knowledge.

Dr. HEDRICK. I think we have had some evidence before this committee that they are being used in other sections.

Mr. KLEINFELD. Mostly experiments, Doctor.

The CHAIRMAN. Anything else?

Mr. HORAN. No questions.

The CHAIRMAN. That is all, Mr. Herrmann. Thank you.

Mr. KLEINFELD. Our last witness is Mr. Jean Martin of Coty, Inc.

The CHAIRMAN. I believe you were sworn in the other afternoon.

Mr. MARTIN. That is right.

The CHAIRMAN. You may proceed.

TESTIMONY OF JEAN MARTIN, CHIEF CHEMIST, COTY, INC., NEW YORK, N. Y.

Mr. KLEINFELD. Mr. Martin, what is your position with Coty?

Mr. MARTIN. I am chief chemist, Coty, Inc., 423 West Fifty-fifth Street.

Mr. KLEINFELD. And as chief chemist, generally speaking, what are your duties?

Mr. MARTIN. My duties are research for new products, control of fabrication and general direction of the laboratories.

Mr. KLEINFELD. Will you read your statement, please.

Mr. MARTIN. As requested in your telegram of December 7, 1951, we are listing below all data you require.

Various products manufactured or distributed by Coty, Inc.: Coty, Inc. has been manufacturing and distributing in the United States since 1922, a line of perfumes and cosmetics, including perfume, toilet water, cologne (liquid and solid), hair lotions, brilliantines, face powder, dusting powder, talcum, sachet, cleansing creams, conditioning cream, eye cream, different lotions for the general care of the skin, lipsticks, rouges, compacts, soaps, deodorants, eye shadow, mascara, eyebrow pencils, suntan oil, suntan lotion.

(The ingredients contained in these products are listed in the files of the committee.)

It is our constant endeavor to obey and live up to the letter and spirit of the general regulations of the Federal Food, Drug, and Cosmetic Act, with special reference to chapter 4, section 601, (a), (b), (c), and (d).

To achieve this end, we operate in the following manner: Before any raw materials are purchased for use in the manufacture of our products, they are first carefully selected and then submitted to analysis in our own laboratories by competent analytical chemists.

Our standards of purity are USP, TGA standards, or better. When such standards do not exist, the samples are analyzed according to accepted practice and usage, or we devise our own methods of analysis. When necessary we use the methods of the AOAC (Association of Agricultural Chemists), whose bulletins we receive regularly.

We again analyze the raw materials when they are delivered to our plant, before we use them in our manufacture. Consequently, no material can be used in production unless it has been approved by our analytical laboratory. Records of such analyses are carefully kept.

The manufacture of our different preparations is constantly supervised by competent, graduate chemists and checked at the various stages of production. Samples of each batch are taken and preserved for future reference. Periodic tests are made by an independent outside laboratory, to verify whether or not our products maintain themselves in a good state of preservation.

When we are working on the development of a new product, two things may occur: (*a*) If the raw materials are the same ones we have used for years, we simply make new combinations with these previously approved and tested products. In this case, we check as the formulation progresses, and since it takes a long time to develop a satisfactory product, we are constantly aware of the possibility of reaction of the product on the skin. (*b*) If, however, we contemplate using a new raw material in a new formula, we ascertain that it is safe

by making inquiries about it to the manufacturer, to outside, independent laboratories, and to FDC officials, if need be; this with a view toward discovering whether any history exists about the product in question, such as possible irritating properties, safe considered limit of use, et cetera.

When we feel confident that the new chemical is safe, we then study the possibility of its incorporation in a new formula. Thorough tests for sensitivity and primary irritation are conducted on a cross-section of several hundred individuals by a well-known, reputable, independent, toxicological laboratory, according to its own standard methods. After the tests are completed, we abide scrupulously by the conclusions reached by the testing laboratory.

We have available records of such practice in our organization as far back as 1929.

If, after these preliminary steps, the finished product is found to be nonirritant and nonsensitizing, we then proceed to test its cosmetic value on several hundred persons selected at random.

We feel that our methods of testing, developing and processing our products are entirely adequate to protect both the public and ourselves.

This statement is proved by the record of our products' liability insurance, which shows that for any given year, the number of registered claims against us have been less than one per million packages sold.

In our opinion, the Federal Food, Drug and Cosmetic Act, as it now stands, is entirely adequate to protect the public if diligently enforced. We believe, however, that the regulations governing the certification of colors are too strict, and we respectfully recommend that they be amended to make available to cosmeticians a wider, more varied and brighter range of shades and colors.

Mr. KLEINFELD. Mr. Martin, are Coty's products submitted to the American Medical Association committee on cosmetics?

Mr. MARTIN. What is that?

Mr. KLEINFELD. Are your products submitted to the committee on cosmetics of the American Medical Association?

Mr. MARTIN. No, sir, we do not submit them. If need be, we will take expert advice from doctors, just like we take expert advice from other people when we need it, but we do not submit any of our formulae to the AMA.

Mr. KLEINFELD. Your company makes soaps; is that correct?

Mr. MARTIN. No, sir, we distribute soaps. We have soaps made for us by other reputable manufacturers.

Mr. KLEINFELD. Do you know whether the reputable manufacturer makes, with respect to his soaps, the kind of tests you make on your cosmetics?

Mr. MARTIN. We know by experience because we have been dealing with the manufacturer for years, and the soaps they make are of excellent quality and have always been satisfactory.

Mr. KLEINFELD. But you have never asked them what tests they actually make or have made?

Mr. MARTIN. Well, we know by experience and analyses what their soaps are made of which they make for us, which are soaps in the sense they are simple combinations of vegetable oils with some lye solution, and from time to time we test to see that the soaps are correct and as they should be.

Mr. KLEINFELD. If the company which manufactures your soaps were to make any changes in the formulation, would you want to know about it?

Mr. MARTIN. We would be advised automatically.

Mr. KLEINFELD. Would you then ask that manufacturer what tests he had made with the new formula?

Mr. MARTIN. Well, if the soap made by them was made according to the standard practice of soap, we certainly would not, because normal soaps have been made and used for years, and we know what they do. But, of course, if some new detergent were contemplated to be used, we first would decide whether we want that or not, and then if we did, we certainly would ask for tests to be made.

Mr. KLEINFELD. In other words, if some new or different substance were being employed in the soap, you would want the same precautions to be taken as with any other cosmetic; is that right?

Mr. MARTIN. We would, provided that the material is different from a soap as we have known soap until the advent of this new one.

Mr. KLEINFELD. Are you saying that all soaps are really the same?

Mr. MARTIN. Well, the definition of a soap, as we know it, is the saponification of vegetable or animal fats with lye solution. Soaps as such, when properly made for the cosmetic industry, have been used and known for years and have never caused any undue trouble. We know by experience that they are safe.

But since these new detergent products have come, we can say that a soap which contains a new detergent is not a soap in the same vein as we used to know soaps.

Mr. KLEINFELD. But if a soap doesn't contain a detergent, you think that one is just as good as another?

Mr. MARTIN. Provided the tests of good manufacture of soap are used, yes, which always happens in the cosmetic industry.

Mr. KLEINFELD. Soaps are more or less alike?

Mr. MARTIN. Yes, the ordinary soaps are more or less alike.

Mr. KLEINFELD. But if they do use some different ingredient, something not used before, you would recommend that the same kind of testing be employed as with other cosmetics; is that right?

Mr. MARTIN. Yes, we would.

Mr. KLEINFELD. Do you know any reason, then, why soaps should be specifically excluded from the definition of cosmetics in this law?

Mr. MARTIN. Well, my point is that as long as soaps are what they used to be, as I explained before, I don't see any reason why they should be included. But if soaps take a new meaning and have to include all of these new class of detergents which have come to us in the last few years, I think that they should be included. I wouldn't say that. I would say that the detergents, themselves, should be tested before they are used in the soaps. It is a question of the detergent itself as a chemical to be tested rather than the soap with detergent in it. It seems to me that the detergent has to be given a clean bill of health.

Mr. KLEINFELD. But putting aside for the moment detergents, aren't various perfumes and different substances used in soaps from time to time?

Mr. MARTIN. Yes, but you see we all know that you need some special ingredients to be used for soap perfuming, and we all do so.

If you think about a soap with a perfume, with a perfume material which would not be considered safe for that type of manufacture——

Mr. KLEINFELD. That is conceivable?

Mr. MARTIN. Everything is conceivable, but as a practice by the industry it is not done.

Mr. KLEINFELD. Aren't soaps sometimes used for shampooing hair?

Mr. MARTIN. Yes, sir.

Mr. KLEINFELD. And different manufacturers do use different types of ingredients from time to time in their soaps; do they not?

Mr. MARTIN. Yes, they do.

Mr. KLEINFELD. On page 3 of your statement, Mr. Martin, in item 3, you talk about the testing of all your raw materials.

Mr. MARTIN. Yes.

Mr. KLEINFELD. What kind of testing do you do with your finished product?

Mr. MARTIN. Well, first, before we formulate the sample all materials are tested again, and as the finished formula is made under the supervision and control of plant chemists, we evidently know what does go into the formula is exactly what has been tested before the formula was assembled, and we know they are pure and harmless when the finished formula is made.

Then we have tests showing that the formula is similar to the accepted standards for consistency, for shade, for color, for emulsion, and also we have tests made to be sure that the formulation will not go bad later on, that in time we shall not have any deterioration of the formula by bacteria or getting rancid or things like that. We have shelf tests and keep records for the formulations for months and months, and we have records of all of that.

Mr. KLEINFELD. Mr. Martin, those are all tests made by the chemist, from the viewpoint of a chemist?

Mr. MARTIN. Yes.

Mr. KLEINFELD. What tests are made on the finished product to determine that it won't hurt anybody?

Mr. MARTIN. It won't hurt?

Mr. KLEINFELD. That it won't hurt the consumer?

Mr. MARTIN. Well, the tests have been made previously by the testing laboratory on a standard formula.

Mr. KLEINFELD. Pardon me. I am not sure whether I made myself clear. You say you test all your raw materials?

Mr. MARTIN. Right.

Mr. KLEINFELD. Now you are getting to the point where you put the raw materials together?

Mr. MARTIN. Yes.

Mr. KLEINFELD. And you have a product. Let's say it is a toilet water or hair lotion.

Mr. MARTIN. Yes.

Mr. KLEINFELD. You have the finished product—a hair lotion. What do you do with the hair lotion so that you can reach a determination in your mind, and in the mind of your company, that it is safe to use this hair lotion?

Just exactly what do you do?

Mr. MARTIN. Well, we don't do any more than be sure that the formula which we make is exactly the same for which we had accepted the standard and which had been tested.

Let me make myself clear. Let's take a face powder. In face powder we use materials known by everybody—talcum, zinc oxide, and several other things. This formula is an accepted formula. We know very well every time we make—we mix all these ingredients which are absolutely known to be harmless and which have been analyzed to see they follow the USP standards, or whatever standards we have, and we know every time we make a formula like that there is no reason for it to harm the public.

So there is no use to make further tests than those which are made for the acceptance of the formula, don't you see?

Mr. KLEINFELD. Then you don't make any tests on the finished product from the viewpoint of what possible effect the finished product can have on the consumer; is that not correct?

Mr. MARTIN. We would if we made a change in the formulation by adding a new ingredient or by adding something of which we don't know the reaction. Then, of course, tests would be made; but as far as regular production goes of a given standard product, we do not make such tests. It is unnecessary.

Mr. KLEINFELD. Let me ask you again. I want to find out what your accustomed business pattern is. Whenever you get up a new product, any product that has not been used before, or whenever you change the formula of an existing product, do you make any specific safety tests?

Mr. MARTIN. We definitely do.

Mr. KLEINFELD. Just what tests do you make?

Mr. MARTIN. I will give you an illustration. We were ready to put a new product on the market sometime ago, and the product had been completely tested by us first and by an outside laboratory who said it was all right.

Mr. KLEINFELD. How was it tested?

Mr. MARTIN. It was tested on patch tests on human beings by this outside laboratory, which took several weeks to make tests, and came back to us with the answer the product is safe, you can go ahead and use it. So when we were ready to get into manufacture, we found out that one of the materials was not available any more, so we had to change our formula just for one raw material. We began reformulating the product, and when we were satisfied the product was going to perform the way we wanted we sent it back to the same laboratory, telling them what change had been made in the formula and to have the product completely tested again as if nothing had happened before.

Mr. KLEINFELD. Then you are saying that whenever you have a new product or change of formulas you do have somebody make safety tests?

Mr. MARTIN. Oh, yes; and by outside laboratories, so we have an opinion which is not a prejudiced one, as to whether it is safe or not.

Mr. KLEINFELD. What kind of facilities does this independent laboratory have for testing your products?

Mr. MARTIN. It is one of the most important laboratories in the East.

Mr. KLEINFELD. What kind of personnel do they have?

Mr. MARTIN. They have dermatologists, physiologists; they have doctors. One of the best laboratories we know of. They have been very carefully selected.

Mr. KLEINFELD. That is the general procedure?

Mr. MARTIN. Yes.

Mr. KLEINFELD. You feel it is important that that procedure be followed?

Mr. MARTIN. As far as we are concerned, we certainly do.

Mr. KLEINFELD. Would you feel safe in putting out a new cosmetic without that procedure having been pursued?

Mr. MARTIN. It all depends. As I said, if we use old raw materials which have been considered and known to be safe from way back, we certainly do not do that because it is useless.

Mr. KLEINFELD. You don't do what?

Mr. MARTIN. We don't go to the testing laboratories to have the formula tested, because we know that it is made from safe products, and we check on it, as I said, as we go along with the formulation. When we build up the formulation we have dozens of tests performed every day on people in the plant and the chemists themselves.

If there is any doubt at any moment that anything could happen, which isn't likely, then we would do something about it.

Mr. KLEINFELD. In other words, when you come to a conclusion that the particular ingredients to be used in a new product have been shown to be safe, you don't submit it to this testing laboratory?

Mr. MARTIN. No; we do not.

Mr. KLEINFELD. Who makes the decision in your organization that these materials are entirely safe?

Mr. MARTIN. Well, first we have materials which have been used in the company since the company existed, which is 40 years. We have made cosmetics in that company since over 20 years. And we know by common practice and knowledge that a lot of products are completely harmless—like mineral oil and lanolin and beeswax and what not. So when we make simple combinations, or different combinations of those products we know with absolute safety that nothing will happen, and it is useless to spend the time and money to do something which wouldn't protect the public any more than it is protected by acting as we do.

Mr. KLEINFELD. Suppose you have an ingredient which is a wetting agent.

Mr. MARTIN. Yes.

Mr. KLEINFELD. Which you are assured by the manufacturer is safe and which you believe to be safe and which is safe. And supposing you have another substance, let us say a quarternary compound, which its manufacturer tells you is quite safe. Are you in a position to say, therefore that it is a logical conclusion that if you put the wetting agent together with the quaternary compound the combination will be entirely safe?

Mr. MARTIN. Well, of course, I must take the question in sections. First, you say if the manufacturer tells me the product is safe. I don't think he will.

Mr. KLEINFELD. Let's say you make tests and you conclude this wetting agent by itself is safe.

Mr. MARTIN. Yes.

Mr. KLEINFELD. In the concentration used.

Mr. MARTIN. Yes.

Mr. KLEINFELD. Suppose you find also that the second product which you are going to use, this quaternary compound, is also safe.

Must it follow that when you put these two substances together the finished product necessarily is safe?

Mr. MARTIN. Well, in this case, of course, I have no knowledge, because I never used the particular combination you speak of. It all depends, of course, whether a reaction can be expected or can be had between two products to make a new combination of chemicals which may not be safe.

Mr. KLEINFELD. Isn't that possible?

Mr. MARTIN. It is possible, certainly. But to go further—the products I speak of in our formulation are known not to react together in a manner that maybe some quaternary ammonium compound may react with a detergent.

Mr. KLEINFELD. That can only be known, is it not true, by making tests on the finished products?

Mr. MARTIN. No. This could be had by making the reaction between the two products themselves before you put them into the combination and finding out.

Mr. KLEINFELD. You have to put the two products together, do you not, to determine whether that finished product will or will not cause any damage? Isn't that true?

Mr. MARTIN. That wasn't the question. The question was whether a detergent mixed with a quaternary ammonium compound, the two products being safe alone, might be considered a different combination. I will go further—many quaternary compounds aren't safe by themselves, and I don't think any of them is safe above certain limits, and I understand there are some very sharp limits above which quaternary ammonium compounds may not be safe by itself.

Mr. KLEINFELD. As a general matter, Mr. Martin, isn't it a fact from the viewpoint of the chemist, which you are, that although you may be entirely satisfied in your own mind that substance A and substance B individually are safe, you can't conclude as a matter of course that the composite substance composed of both those ingredients is necessarily free from some injurious effect, particularly when you are dealing with a wetting agent?

Mr. MARTIN. No; I would not. I would not for this reason: Detergents is a world in itself. You have hundreds of detergents, and each one must be taken on its own entity and mixed with whatever the quaternary ammonium compound you are thinking of—also, there are so many of them—to see what is going to happen between those two.

In other words, each one must be tested on its own case. I wouldn't offhand say if I mix any detergent with any quaternary ammonium compound anything would happen, because I don't know.

Mr. KLEINFELD. You don't know?

Mr. MARTIN. No.

Mr. KLEINFELD. What purpose does a wetting agent serve?

Mr. MARTIN. A wetting agent?

Mr. KLEINFELD. Yes.

Mr. MARTIN. Well, they serve to lower the surface tension and to allow cleansing or to allow emulsification.

Mr. KLEINFELD. And why is it used in combination with other substances in cosmetics?

Mr. MARTIN. Well, I suppose if you want a certain effect and you feel that you can get it with a detergent better than with something else, you may consider the use of a detergent.

Mr. KLEINFELD. What effect may a wetting agent have upon the penetrating effect of other ingredients in the cosmetics?

Mr. MARTIN. I really don't know, because each one, as I say, is a specific product, and I can't say offhand. You can't speak in generalities.

For instance soap, if you wish to say it is a detergent, then you have detergents which are good, you have some which are bad, you have some which are indifferent. So what it is going to do for me may be bad, may be good. You have to find out.

Mr. KLEINFELD. Isn't it a fact that a wetting agent generally is used because it permits greater penetration of the product?

Mr. MARTIN. No; not necessarily. It is used usually because, as I say, it lowers surface tension and helps faster cleaning, emulsification. Some of them aren't used necessarily for cleansing purposes. Some detergents are used simply to make some kinds of emulsions.

Mr. KLEINFELD. In certain instances it is used to permit a greater penetration; is it not?

Mr. MARTIN. Yes.

Mr. KLEINFELD. So if it permits a greater penetration of some other substance you have to make tests on the finished product, do you not?

Mr. MARTIN. Yes.

Mr. KLEINFELD. And these tests should be made by careful cosmetic manufacturers?

Mr. MARTIN. Yes.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Hedrick, do you have any questions?

Dr. HEDRICK. No.

The CHAIRMAN. I think that is all.

We will recess until 10 o'clock tomorrow.

(At 3:30 p. m., a recess was taken until Tuesday, January 15, 1952, at 10 a. m.)

CHEMICALS IN FOODS AND COSMETICS

TUESDAY, JANUARY 15, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS IN FOODS AND COSMETICS,
New York City, N. Y.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess.; continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 10:15 a. m., in room 128, United States Courthouse, New York City, N. Y., Hon. James J. Delaney (chairman) presiding.

Present: Representatives Delaney of New York; Hedrick of West Virginia; and Horan of Washington.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will be in order.

Call the first witness.

Mr. KLEINFELD. Dr. Jolliffe.

The CHAIRMAN. Your name and address?

Dr. JOLLIFFE. Norman Jolliffe, 2 East 103 Street, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF NORMAN JOLLIFFE, M. D., REPRESENTING THE NEW YORK ACADEMY OF MEDICINE, NEW YORK, N. Y.

Mr. KLEINFELD. Dr. Jolliffe, when did you receive your medical degree?

Dr. JOLLIFFE. 1926, from the New York University and Bellevue Hospital Medical College.

Mr. KLEINFELD. And you have practiced medicine since then?

Dr. JOLLIFFE. I have practiced medicine since then; yes, sir.

Mr. KLEINFELD. What did you do subsequent to your obtaining your degree of doctor of medicine?

Dr. JOLLIFFE. I interned and was a resident physician until 1930 at Bellevue Hospital. Then I was instructor in physiology for 2 years in the department of physiology at New York University, and then I was chief of the medical service, psychiatric division, Bellevue Hospital, from 1932 to 1945. I was instructor, assistant professor, and associate professor of medicine at New York University from 1930 until 1945. Then I was associate professor of public health from 1945 to possibly 1949, and then from 1949 until the present time I hold the same position at the school of public health, Columbia University.

Since 1949 I have been director of the bureau of nutrition of the department of health for New York City.

Mr. KLEINFELD. Do you hold that position now?

Dr. JOLLIFFE. Yes.

Mr. KLEINFELD. Are you a member of the New York Academy of Medicine?

Dr. JOLLIFFE. Yes, sir; a member of the New York Academy of Medicine. I have been a member of the Food and Nutrition Board of the National Research Council. I am a diplomate of the American Board of Internal Medicine and of the American Board of Public Health and Preventive Medicine; member of several societies—American College of Physicians, American Society of Clinical Investigation, State, county, and national American Medical Associations.

Mr. KLEINFELD. Has your specialty been in the field of nutrition?

Dr. JOLLIFFE. Yes, sir.

Mr. KLEINFELD. Is your statement presented on behalf of the New York Academy of Medicine?

Dr. JOLLIFFE. Yes; it is presented on behalf of the committee on public health relations of the New York Academy of Medicine.

Mr. KLEINFELD. What is the New York Academy of Medicine?

Dr. JOLLIFFE. The New York Academy of Medicine is an association of physicians to promote the general welfare from a medical and a public health point of view of the people of New York City, and to encourage education and training of physicians.

Mr. KLEINFELD. Do you know how long the academy has been in existence?

Dr. JOLLIFFE. It is over a hundred years.

Mr. KLEINFELD. Will you please read your statement, Doctor?

Dr. JOLLIFFE. The statement is in behalf of the committee on public health relations of the New York Academy of Medicine.

The committee on public health relations of the New York Academy of Medicine welcomes the invitation of the Congressional Committee To Investigate the Use of Chemicals in Food Products to present its views concerning the increasing utilization of chemicals in the Nation's food supply and the desirability of legislation which would require the determination of their freedom from toxic effects to the satisfaction of the Food and Drug Administraton before such chemicals are utilized in foods.

For more than a century the New York Academy of Medicine has concerned itself with the promotion of public health; since 1911 through the work of its standing committee on public health relations. In the course of its investigations of food and drugs, representatives of the committee have testified on several occasions before various congressional committees considering the problem, and these activities undoubtedly contributed to the enactment in 1938 of the present Food, Drug, and Cosmetic Act.

Recently this committee of the New York Academy of Medicine has studied the testimony given at the hearings of this select committee between September 14 and December 15, 1950. From this testimony and from our own knowledge and experience, we are convinced that some chemicals introduced into foods during their production, preparation, processing, and packaging may constitute a serious hazard to health. Also, some pesticides and insecticides used incidental to

the production of food may accidentally contaminate it for human consumption to such an extent as to be potentially harmful to the consumer.

For these reasons, the committee on public health relations of the New York Academy of Medicine recommends that Congress amend the Food, Drug, and Cosmetic Act so that all chemicals used in or on foods shall be subjected to investigation required by the Food and Drug Administration for the determination of safety for human consumption prior to their use in or on foods distributed and sold in interstate commerce. It is further recommended that the several States adopt similar regulations for foods produced and used within the States.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Jolliffe, in the Food, Drug, Cosmetic Law Journal of November 1951, volume 6, No. 11, there appears an address by Charles W. Crawford, Commissioner of the Food and Drug Administration, delivered before the Division of Food, Drug, and Cosmetic law of the American Bar Association on September 19, 1951. This address was entitled "Gaps in Consumer Protection Under the Food and Drug Law."

In part this is what Mr. Crawford said, and I quote:

> It would be both unfair and incorrect to appraise this problem on the assumption that we have an irresponsible chemical industry and an irresponsible food industry both calloused to the health of consumers. Nor can we appraise it on the assumption that there is no clear and present danger. The facts rule out both these assumptions. But they show that there is a fringe of the careless or ignorant or unscrupulous who have used or are now using chemicals in food without sufficient testing to be reasonably certain that they will not impair the health of consumers. That the dramatic equivalent of the elixir sulfanilamide disaster has not occurred in the food field speaks volumes first for the conscientiousness of the food industry generally, and second, for the providential luck of its fringe operators and of the public. We have had some narrow escapes.

Is that generally in accord with the statement which you just read to the committee?

Dr. JOLLIFFE. Yes, that is.

Mr. KLEINFELD. Could you elaborate on it? For example, Mr. Crawford spoke about the elixir sulfanilamide incident, and I think, as you know, that caused the death of over a hundred people. Is that correct?

Dr. JOLLIFFE. Yes.

Mr. KLEINFELD. And that led to the enactment of the new drug section of the present act.

Dr. JOLLIFFE. That is right.

Mr. KLEINFELD. Is it true that you are concerned that the same thing might possibly happen in the food field?

Dr. JOLLIFFE. I would hazard a guess, Mr. Counsel, that with the rapid expansion of the chemical industry—and, frankly, many people including myself think we are only at the begining of the growth and usefulness of this industry—that without very definite regulation a similar tragedy may occur, and it may be a far worse one than the sulfanilamide tragedy, because these chemicals will be put in the food that will be more widely used and consumed than, say, a drug that is used only for sick people.

I would think that the industry, meaning the chemical industry or food industry in general, would welcome an outside authority,

a nonprejudiced outside authority, to pass judgment upon the adequacy of safety tests that responsible members of industry itself uses before they apply it to food. Certainly the chemists and scientists in these organizations can be put under tremendous pressure by management and many of them, I am sure, would welcome the final judgment of an outside source whether or not the addition of a new chemical may or may not constitute a health hazard.

Mr. KLEINFELD. Doctor, suppose you were consulted with respect to the prospective use of some ingredient intended for use in a wide variety of foods, some of them staple foods, eaten, perhaps every day and perhaps every meal, and you and your assistants or fellow workers came to the conclusion that the data available to you on the toxicity, tolerance, metabolic rate, and nutritive value of these ingredients were insufficient to permit a final judgment as to the safety of the substances for use in foods. What would your view be in such a situation?

Dr. JOLLIFFE. My view would be that it should not be used until there is a fair unanimity of opinion that it would not constitute a health hazard.

Mr. KLEINFELD. Well, on November 9, 1951, the Food Protection Committee of the National Research Council released a statement entitled "Statement on the Use of Surface Active Agents in Foods."

Apparently there are two types of these surface agents, the mono- and diglycerides of fatty acids and the esters of nonalcoholic glycerols.

Apparently also these two groups of surface active agents are used in many diverse foods, such as bread and other bakery products, meats, margarine, cake mixes, ice cream, and other types of foods which are widely consumed.

This statement said, in connection with the use of both of these types of surface active agents, as follows:

> It is our considered opinion that the data available to us on the toxicity, tolerance, metabolic rate, and nutritive value of these surface active agents proposed for use in ice cream are insufficient to permit a final judgment as to the safety of the substances for use in foods.

Do you think that the widespread use of such substances in such a wide variety of foods raises a serious problem if a scientific body cannot conclude that they are safe?

Dr. JOLLIFFE. I would certainly hesitate to say that they are safe if somebody such as that can find no positive evidence that they are. I would certainly think that would constitute a danger signal.

Mr. KLEINFELD. And is the problem accentuated if these substances are used in staple foods, like bread and other bakery products, consumed widely?

Dr. JOLLIFFE. Yes; surely.

Mr. KLEINFELD. If these substances are being widely used before it is known definitely that they are actually free from doubt as to safety, that raises a serious problem, doesn't it?

Dr. JOLLIFFE. It would raise a serious theoretical, and probably a practical, problem.

Mr. KLEINFELD. Dr. Jolliffe, have you been associated with the pharmaceutical industry?

Dr. JOLLIFFE. I have acted as consultant on several occasions.

Mr. KLEINFELD. Are you familiar with the new drug section of the present law?

Dr. JOLLIFFE. In general; yes, sir.

Mr. KLEINFELD. That has been in existence since 1938, when the act was passed; is that not true?

Dr. JOLLIFFE. That is right.

Mr. KLEINFELD. If you can tell us, how has the industry operated under that new drug section? Has it hampered their efficiency, their growth, their progress?

Dr. JOLLIFFE. As one outside the industry, but one that acts in a consulting capacity to them, and looking at it from outside rather than inside the industry, I do not think that there is hardly any industry in this country that has shown more rapid progress since 1938 than the pharmaceutical industry, certainly they have not been hampered in their growth, as evidenced by the figures, and they have had to give positive proof of the nonhazardous nature of a new drug, considering its purpose and directions for use before it is marketed. That fact has not hampered the growth of the pharmaceutical industry.

Mr. KLEINFELD. I have here a book entitled "Historic Meeting To Commemorate Fortieth Anniversary of Original Federal Food and Drugs Act," published in 1946 by the Commerce Clearing House, Inc. It reports a meeting held under the auspices of the Section on Food, Drug, and Cosmetic law of the New York State Bar Association.

One of the papers read there was entitled "Its"—meaning the Food and Drug Act—"Basic Value to Drug Industry" by S. DeWitt Clough, chairman of the board of the Abbott Laboratories and, in part, this is what it said:

> And it may be added here as my second point that the administration of these laws during the past 40 years, plus the aid of other governmental agencies and the cooperation of the pharmaceutical industry, about which I shall speak later, has created in the minds of the medical profession, as well as in the consciousness of the laity, an increased confidence in the purity, the accuracy, and dependability of pharmaceutical products for the purposes claimed on the labels. This is particularly true since the amended act of 1938 went into effect. That this confidence is constantly becoming greater is proved by the fact that professional acceptance and recommendation of pharmaceutical products, advertised to physicians, now outweigh the influence of large sums spent in product advertising directly to the public.
>
> Always there may be marginal manufacturers who are less concerned about research and scientific control than they are interested in sales volume and profits, but I believe that this type of firm is rapidly passing out of the picture. It has been demonstrated, in the pharmaceutical field, that there can be no permanent success, no long-continued growth, without a long-range research program and a well-organized, sufficiently staffed control department.

Are you generally in accord with those statements?

Dr. JOLLIFFE. Yes, sir; I am.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. No questions.

The CHAIRMAN. Thank you, doctor. We appreciate your coming. I am sorry more of the members are not here to get the benefits of your views.

Dr. JOLLIFFE. Thank you.

The CHAIRMAN. Call the next witness.

Mr. KLEINFELD. Dr. Sevringhaus.

The CHAIRMAN. Your name and address, Doctor?

Dr. SEVRINGHAUS. Elmer L. Sevringhaus, Essex Falls, N. J.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF ELMER L. SEVRINGHAUS, M. D., DIRECTOR OF ENDOCRINOLOGY AND METABOLISM, MEDICAL CENTER, JERSEY CITY, N. J.

Mr. KLEINFELD. Dr. Sevringhaus, where did you obtain your degree of Doctor of Medicine?

Dr. SEVRINGHAUS. Harvard Medical School, 1921.

Mr. KLEINFELD. And you have practiced medicine since then?

Dr. SEVRINGHAUS. Since that time I have practiced medicine.

Mr. KLEINFELD. What societies are you connected with?

Dr. SEVRINGHAUS. I am a member of the Essex County, the New Jersey State, and the American Medical Associations, the American Society for Clinical Investigation, the Association of American Physicians, the American College of Physicians, the American Society for Study of Internal Secretions, the American Institute of Nutrition, the American Society of Biological Chemists, the New York Academy of Medicine.

Mr. KLEINFELD. Have you specialized in any particular field?

Dr. SEVRINGHAUS. My special work throughout this period has been in the field of nutrition and of endocrinology and some specialties in internal medicine.

Mr. KLEINFELD. How long have you specialized in those fields?

Dr. SEVRINGHAUS. Since 1922.

Mr. KLEINFELD. Have you contributed papers in those fields to the professional publications?

Dr. SEVRINGHAUS. Yes; a considerable number.

Mr. KLEINFELD. And are you now director of endocrinology and metabolism at the Medical Center, Jersey City in New Jersey?

Dr. SEVRINGHAUS. That is correct.

Mr. KLEINFELD. Will you please read your statement, sir?

Dr. SEVRINGHAUS. My experience with using measured doses of estrogenic hormone preparations in the treatment of women extends over the past 22 years. In addition to administering these hormones orally and by injection into the muscle or under the skin of patients, I investigated the possibility of administering solutions of the hormones in concentrated ethyl alcohol. This proved to be a very effective way of administering the hormones. Subsequently, I satisfied myself that the hormone could be introduced by applying it in solution in oily and waxy materials, such as are used in ointments and cosmetic creams. The intensity of effect by any one of the above-mentioned methods was of the same order of magnitude as for the others. In other words, any one of these methods could be used as a practical program in the treatment of disorders of women that required estrogenic hormones.

During the period of this study, there arose mention of the possibility that the application of the estrogenic hormone on the surface of the skin might be a significant causative factor in the development of cancer. Similar fear has been expressed for the use of the hormone by any of the other routes mentioned. To the best of my knowledge, no conclusive evidence has yet been adduced that such a causative rela-

tionship exists. Certainly my own experience never provided any reason to be fearful of this danger.

My professional experience with the use of these materials, administered by any route including that of cosmetic or therapeutic ointment, had indicated that when the dosage is unduly large or continued for an unduly long time, it may result in irregularities in the menstrual rhythm of women who are otherwise having regular menstruation, or that it may reestablish what is apparently a menstrual flow in women who have ceased to menstruate. These phenomena would be considered not only a disturbing nuisance, but in the case of women who are still menstruating regularly, this would undoubtedly lead to some disturbance in fertility, probably temporary in nature, and in any case, the irregularity of menstrual rhythm would simulate other diseases. This would be adequate ground for extensive medical investigations and possibly other therapeutic efforts.

On the basis of this experience and the opinions expressed above, it has long been my feeling that the application of estrogenic hormone through cosmetic agents or ointments is a subject which requires extensive professional study, and that the use of these materials ought to be under professional supervision and regulation of dosage. There are sufficient advantages to this method of supplying estrogenic hormones so that I do not believe it should be prohibited or made unnecessarily difficult. It is my hope that the attention directed to the subject may stimulate more extensive efforts by manufacturers and physicians in exploring this important field.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. As I understand your statement, Doctor, apparently the important problem in your opinion is the question of the supervision and regulation of dosage; is that correct?

Dr. SEVRINGHAUS. That is correct.

Mr. KLEINFELD. And I suppose that is why, in your statement to the committee of December 10, 1951, you said in part,

> I think the crux of the whole matter comes in this failure to have intelligent supervision of dosage. As a consequence some women are finding the results of excessive dosage and of irregularly administered dosage. This does not show up in the form of cancer, but of disturbance in menstrual rhythm.

That, in your opinion, is the real problem—the unsupervised administration of the hormone preparations; is that correct?

Dr. SEVRINGHAUS. That is.

Mr. KLEINFELD. Do you think the problem is accentuated, Doctor, if the hormones are contained in various different types of cosmetic preparations which are used on large areas of different portions of the body? For example, we might have one situation where we have a face cream containing a hormone to be used before going to bed, let's say, and to be used perhaps on the face or the face and the neck, and that might contain 10,000 international units of the hormone per ounce, in a little jar containing 2 ounces for use over a 30-day period. That might be one situation.

Now the other situation might be one which encompassed the use of that face cream with the same number of international units of estrogenic hormones, recommended for use on the face, neck, and throat; also the recommended use of a lotion and other creams for use on the hands, elbows, shoulders, and thighs; another preparation containing the same amount of international units of hormones recom-

mended for use as a shampoo; another one for use on the scalp, and another product recommended for use as a base before a woman applies face powder. So that the result might be that for 24 hours a day a woman might have these hormone preparations on comparatively large areas of her body.

Now, does that problem accentuate the possible dangers, in your opinion?

Dr. SEVRINGHAUS. Obviously, since it would be physically impossible for anyone who was not trained in quantitative measurement of ointments, lotions, and creams to determine the daily dose that had been applied by such diversity of products.

Mr. KLEINFELD. And might the method of applications create a more serious problem. Supose, for example, some women who perhaps were not properly warned or cautioned, were to use more than is customarily advised, and rubbed it in for greater periods of time and on greater portions of the body, would that similarly create a more serious problem?

Dr. SEVRINGHAUS. Obviously, the greater area to which the ointment is applied, the larger the amount that is apt to be absorbed.

Mr. KLEINFELD. Have you any affirmative recommendations to the committee in connection with the problem of the use of hormones in various cosmetic preparations?

Dr. SEVRINGHAUS. Well, I am not prepared to make any definite recommendations. I merely hope that the recommendation will include such provisions as are comparable to those in the current food, drug, and cosmetic law as applied to hormones in drugs.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Doctor, I was wondering whether you have any experience with radioactive ointments or creams?

Dr. SEVRINGHAUS. I have none.

The CHAIRMAN. Do you know that such ointments and creams do exist?

Dr. SEVRINGHAUS. Yes; I have heard of them.

The CHAIRMAN. And they contain the alpha rays?

Dr. SEVRINGHAUS. I do not happen to know what they contain.

The CHAIRMAN. All right.

Dr. Hedrick?

Dr. HEDRICK. Doctor, are estrogenic hormones in creams readily absorbed through the human skin?

Dr. SEVRINGHAUS. I am convinced of that by my own experience with patients; yes.

Dr. HEDRICK. About what percentage of the estrogenic hormone would be absorbed?

Dr. SEVRINGHAUS. I have no data as to percentage, but the impression gained from my observation is that it is 100 percent absorbed if the ointment is not rubbed off too quickly.

Dr. HEDRICK. About how long would it take for 100 percent to be absorbed?

Dr. SEVRINGHAUS. I have no data that would give a definite answer, so I could not tell whether it would be absorbed in the course of a half a day or whether it would take several days; but since ointments applied properly on dried skin will be so incorporated into the texture of the skin that they can't be rubbed off once they have been applied

that way and rubbed in, the absorption could continue, and it would therefore become accumulative with daily dosages.

Dr. HEDRICK. How many international units would a patient have to absorb in 24 hours for it to be dangerous, in your opinion?

Dr. SEVRINGHAUS. It would be extremely variable. For some women the absorption of 1,000 units per day would create a disturbance such as I have described. For others there might be a tolerance for as much as 10,000 units in a day. There is no set figure that will apply to all women in that way.

Dr. HEDRICK. I imagine in your practice, Doctor, many times you have given 10 or even 20,000 international units for injections?

Dr. SEVRINGHAUS. I have never authorized more than 10,000, but I know it is frequently done in doses as high as 20,000.

Dr. HEDRICK. Have you ever seen any undue effects from a dose of that size?

Dr. SEVRINGHAUS. Just the same type that I have described for the ointment; yes—disturbance of menstrual rhythm, disturbances of fertility produced by injection.

Dr. HEDRICK. Do you think estrogenic hormone lessens the possibility of pregnancy?

Dr. SEVRINGHAUS. I am very sure it may in certain conditions lessen the possibilities of pregnancy at the period during which the hormone is having its effect, which period might extend for 2 or 3 months.

Dr. HEDRICK. What is the injurious effect, generally, on the nervous system to women when they use estrogenic hormones?

Dr. SEVRINGHAUS. It is apt to bring about a state of tension, of lack of ordinary amount of emotional balance and control, consciousness of certain of the vital phenomena, may produce headaches, may disturb sleep; that type of disturbances.

Dr. HEDRICK. What effect do the estrogenic hormone creams have on the skin?

Dr. SEVRINGHAUS. I do not have any experience on that, so all I know about it is what I have read.

Dr. HEDRICK. It is supposed to cause an edema condition of the skin; is that correct?

Dr. SEVRINGHAUS. It could be described that way I suppose.

Dr. HEDRICK. In other words, it increases the fluid in the tissues of the skin.

Dr. SEVRINGHAUS. Fluid content of the tissue. Whether it would go to the extent of edema I don't happen to know.

Dr. HEDRICK. In your experience have you noticed it making women look younger after continued use?

Dr. SEVRINGHAUS. Yes; I have seen that kind of effect.

Dr. HEDRICK. You actually have seen improvement in their looks?

Dr. SEVRINGHAUS. Yes.

Dr. HEDRICK. That is all.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. From your experience, Doctor, is there any connection at all between the use of this hormone and the possibility of the presence or the lack of presence of migraine headaches?

Dr. SEVRINGHAUS. I am sure that there is a possibility of relationship between the hormone supply within the body and the occurrence of headaches. When one specifies a migraine headache he opens up a question of definition which is subject to some debate in the medical

profession. If one limits it to the classical description of migraine headache, I don't know of any connection.

Mr. HORAN. Migraine headaches quite often in many patients are absent during the period of pregnancy, and I just wondered what the over-all effect of estrogenic hormones might be in that field.

Dr. SEVRINGHAUS. One would go there into theory because there is no method of measuring a headache.

Mr. HORAN. But we do look to gentlemen like yourself to help us supply the answers to some of the mysteries of life.

Dr. SEVRINGHAUS. Yes.

Mr. HORAN. And you have pointed out the danger of estrogenic hormones unless properly used and properly administered. You do not believe they should be stopped?

Dr. SEVINGHAUS. By no means.

Mr. HORAN. Or denied to the use of the medical world?

Dr. SEVRINGHAUS. No.

Mr. HORAN. That is what we are trying to get at in this committee. You understand that?

Dr. SEVRINGHAUS. Yes.

Mr. HORAN. In your last sentence you state that you hope that these hearings are an attempt to mobilize the thinking through this committee of the medical field and manufacturing field, and may stimulate more extensive efforts, as you say, by manufacturers and physicians in exploring this important field.

Now we are all for that, but our particular job is where does the Government and its facilities fit into this picture.

For instance, what is your feeling regarding the Public Health Service in this picture?

Dr. SEVRINGHAUS. Well, my feeling is that the Public Health Service's interest would properly be expressed by their encouragement of investigations in this field since they have such a large opportunity and the equipment for the stimulation of investigation in many fields of medicine.

Mr. HORAN. Of course, I agree with you. I think you are being very conservative in your statements. Do you feel that they should carry on experiments or should they coordinate the work that is now being done by manufacturers and persons like yourself, and other facilities that exist in the public or in private experimentation in this field, or what should they do specifically. Because as far as I know, this committee has an open mind on this subject, and we would like to know how best we can take advantage of the things that our society, which has been rather progressive, has already produced. How should we coordinate the things that are being done in the United States?

Dr. SEVRINGHAUS. I am entirely incompetent to write a plan for this coordination, I am sure. My understanding of the responsibilities of the United States Public Health Service is that it has facilities for carrying out research in its own laboratories at Bethesda, Md., that it also has a very large measure of responsibility for the distribution of Federal funds in support of research carried out elsewhere by private physicians, by educational and research institutions or by industry. I do not understand that it has any responsibility for the coordination of such work done elsewhere. And that matter of coordination is a very difficult problem.

Mr. HORAN. Very. That is the reason I am asking you this question.

Dr. SEVRINGHAUS. And I think that the coordination has to be the result of setting up standards of efficacy and safety in the materials that are made available for professional use and for public use without professional guidance.

Mr. HORAN. Well, I like this statement, and I think you are dealing with a field that we ought to know more about, and I think the whole sense of your statement is in that field.

What we want to do, of course, what I want to do personally, at least, is to find out who can tell us the answers or who might be able to tell us the answers and encourage them as your statement indicates. But I hope that the sum total of our work here will be to point out to everyone in this great Nation of ours a procedure so that we will find out these answers and how best to use them for the general good of all of us. I think that is what you mean.

Dr. SEVRINGHAUS. Yes.

Mr. HORAN. And, of course, the question we must answer is how far the Government itself should go, whether we should stay out of it or whether we should move in; and if the Public Health Service is asked to help assist manufacturers and physicians to find these answers, how far they should go in that direction; and we have a very practical thing to answer ourselves.

In certain fields we have called on the Public Health Service to assist us. In the field of the use of pesticides on fruits and vegetables and other foods we are now employing the Public Health Service to find out the answers and how we can make sure that the general public is assured that that which they eat is safe.

Now we felt that we had to have an unbiased body to do this study of what those limits were in that field. In this field we are all working in the dark, and your testimony proves it. That is what you came here to say this morning—that it is long before dawn in our general knowledge in the use of estrogenic hormones. And we want to get out of the darkness here. How are we going to do it, and what is the function of the Government in that field?

Dr. SEVRINGHAUS. Well, the best I can offer is the suggestion that we know a great deal about the activity of the estrogenic hormones no matter how they are administered, that there is certainly not a consensus among medical men who have experience in this field as to the appropriate dose which can be administered safely by a woman without professional supervision. And until such a consensus can develop about the safety of dosage unsupervised, it would seem to me the part of wisdom to interfere with that kind of unsupervised use.

Mr. HORAN. I think that is as far as we can go. Our counsel brought that out pretty plainly, I thought.

That is all, Mr. Chairman.

The CHAIRMAN. Thank you, Doctor.

Mr. HORAN. I want to thank you, too.

Mr. KLEINFELD. Dr. Lubowe.

The CHAIRMAN. Your name and address, Doctor?

Dr. LUBOWE. Irwin I. Lubowe, 1 West Eighty-fifth Street, New York.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF IRWIN I. LUBOWE, M. D., NEW YORK, N. Y.

Mr. KLEINFELD. Dr. Lubowe, where did you obtain your medical degree?

Dr. LUBOWE. New York Medical College, year 1930.

Mr. KLEINFELD. What is your special field?

Dr. LUBOWE. Dermatology.

Mr. KLEINFELD. You are a diplomate of the American Board of Dermatology and Syphilology?

Dr. LUBOWE. That is correct.

Mr. KLEINFELD. And a fellow of the Academy of Dermatology and Syphilology?

Dr. LUBOWE. That is correct.

Mr. KLEINFELD. And a fellow of the American Public Health Association, American College of Allergists, and American Medical Association?

Dr. LUBOWE. Yes.

Mr. KLEINFELD. And a fellow in dematology, New York Council of Surgeons?

Dr. LUBOWE. Yes, sir.

Mr. KLEINFELD. And you are a member of the Society of Cosmetic Chemists?

Dr. LUBOWE. Correct.

Mr. KLEINFELD. How long have you specialized in the field of dermatology?

Dr. LUBOWE. Since 1937.

Mr. KLEINFELD. Will you please read your statement.

Dr. LUBOWE. I wish to take this opportunity of thanking Congressman Delaney, chairman of the House Select Committee on Chemicals, for inviting me to express my views in this very important matter of the relationship of the pharmaceutical, chemical, and cosmetic industry to the general health of the public.

I am a certified practicing dermatologist in the city of New York. I am a member of the dermatological staff of two large New York hospitals, a member of the teaching staff of a New York City medical college, and have been employed by the Bureau of Social Hygiene, New York Department of Health. I am also a pharmaceutical and cosmetic consultant in the clinical evaluation of new products. I have been employed to pretest new pharmaceutical and cosmetic products before their release to the general consumer public by patch testing, patient and consumer usage tests, in order to determine their clinical effect.

In the course of my practice of dermatology, I have been consulted frequently by physicians and patients, for the diagnosis and treatment of diseases of the skin, contact dermatitis, which occasionally appears following the application of pharmaceuticals and cosmetics. I have written many original articles on this subject, which have and will appear in accredited medical journals.

In 1938, the Food, Drug and Cosmetic Act was instituted for the benefit of the patient, consumer, pharmaceutical and cosmetic manufacturers, which is enforced by the Food and Drug Department of the Federal Government. This act became a part of our legislative system after the unfortunate deaths of many innocent people following

the injudicious use of an ethylene glycol base as a vehicle for the dispersion of sulfanilamide derivatives.

For a new pharmaceutical product to be dispensed by the pharmacist to the patient, a drug application must be submitted by the manufacturer with certified clinical and therapeutic reports, accompanied by a minutely detailed list of untoward or toxic reactions which have been encountered or observed after animal, human and clinical trial and research. In this manner, pharmaceutical products which may be toxic, harmful and may cause untold misery are not offered to the public, and are immediately discarded from the commercial roster of new drugs. As a practical result of this preclinical screening, serious accidents, fatalities, body injuries, and undesirable publicity are avoided.

Originally, the word "cosmetic" was defined as a preparation used to beautify and improve the skin and complexion. My interpretation of a cosmetic is a preparation used topically to improve externally, beautify and adorn the skin and its appendages. However, when a cosmetic contains active chemical ingredients as steroids, endocrines, antiseptics, detergents and emulsifiers which may have a biochemical and physiological effect upon the skin, we must then alter our ancient concept of the function of a cosmetic.

If I am to be a little facetious, I would call these products "cosmedics."

As you all know, the skin consists of various layers known as the epidermis, corium and subcutaneous tissues. If a cosmetic in the true sense of the word affects only the outer layers of skin, this preparation can be utilized by the consumer without competent medical or skilled supervision. If it affects the deeper layers of skin, wherein are contained the blood vessels, lymph structures, elastic and collagen fibers and nerves, the probability of absorption and constitutional effects must be considered.

Mr. HORAN. Mr. Chairman, I want to thank you for throwing some light on the difference between cosmetics and medicines and drugs. It has been very confusing to me to understand any great difference between them, because they certainly operate in fields very much adjacent to each other.

Dr. LUBOWE. That is right.

Mr. HORAN. And your testimony here is very helpful to me because I have been troubled with that differentiation. Thank you.

Dr. LUBOWE. In the last decade, the pharmaceutical and chemical industries have produced an abundance of miracle drugs for internal consumption and external use upon the skin and appendages. This new era of antibiotics has been glorified by the production of the sulfa derivatives, penicillin, bacitracin, streptomycin, aureomycin, terramycin, chloromycetin, polymixin, and neomycin. Before these drugs were offered for human consumption, thousands of chemically related compounds were studied and discarded because of their potential toxic effects upon the laboratory animal. Many of the antibiotics can be applied topically on the skin without serious danger. However, toxic manifestations affecting the blood, kidneys and liver when bacitracin, tyrothricin and neomycin are taken internally have been noted.

Several antibiotics when used therapeutically on the skin may cause sensitization and subsequent contact dermatitis venenata as the sulfa,

penicillin, aureomycin and terramycin preparation. We have found that the least productive allergenic antibiotics are tyrothricin combined with bacitracin. They have a synergistic effect with practically no local sensitization. If an antibiotic, which is effective against various strains of bacteria and viruses, is used locally in an ointment form and sensitization follows, this skin reaction predicates against future use of this antibiotic internally.

The introduction of the detergents, emulsifiers and wetting agents have opened a new vista of cosmetic preparations. The detergents can be chemically classified as anionic, cationic and nonionic. The latter group seems to be the most stable of the detergents and least harmful. Basically, the chemical structure of these products are sufonated esters of higher alcohols such as lauryl alcohol, or vegetable oils or sulfonated castor oil.

The polyethylene glycol and polyoxyethylene sorbitan compounds are also being used in cosmetic, pharmaceutical and food preparations as emulsifiers and detergents, and occasionally an unrelated reaction occurs. Sodium lauryl sulfate is known to neutralize lysozyme factor of the gastric juices. In the December 8, 1951, issue of the Lancet, Dr. H. Lehmann reported a change in the prothrombin-time estimation when glassware was washed with alkyl sulfate detergents. This occurs in the laboratory.

These surfactant preparations are incorporated in elegant mixtures to aid in the intradermal penetration of the active ingredients. They are also prescribed by the dermatologists for use as cleaning agents in patients who are sensitive or allergic to ordinary household soap and water. Frequently there is an unexpected reaction following the use of these products, in either cake or liquid form.

A drying of the epidermis is noted after constant use which has to be counteracted by use of petrolatum, mineral oil, lanolin, or cholesterol derivatives. The majority of detergent wetting agents are used in the manufacture of soapless shampoos either in liquid or in cream bases.

Recently, Dr. Boen Swinny in the November–December 1951 issue, volume 9, page 774, of the Annals of Allergy, reported 63 cases of dermatitis involving the periorbital areas following use of detergent cream shampoo. Evidently the eyelids are affected by the rinsing water containing detergents, which come in contact with the skin of the periobital area causing dermatitis venenata. We have observed several cases in our practice. This type of dermatological entity disappears when the shampoo is eliminated.

However, on the other hand we must realize that millions of soapless shampoos are utilized weekly. These shampoos contain the aforementioned detergents, and the incidence of dermatitis is almost minimal. Occasionally, untoward skin manifestations which are usually allergic appear. They do not necessarily indicate that these preparations are harmful for general public use, and should be withdrawn from the commercial market. However, their side effects should be studied in detail.

The quartenary ammonium compounds have proven to be effective antiseptics and bactericides even when utilized in small concentrations of 0.5 to 1 percent. They are used for sterilization of the skin and surgical instruments. If used in larger concentrations, sensitization

may occur. However, they are not being added in formulation of hair lotions and shampoos.

Recently, in dermatological practices I have been consulted for damage to skin and scalp that followed the use of hair dyes. These are manifested by dermatitis of the scalp tissue, falling, drying and brittleness of the hair. In the majority of cases, these untoward reactions followed or preceded the use of cold wave application indicating that there may occur unsuspected chemical reactions, when a hair dye is utilized in conjunction with a cold permanent wave.

We know that the paraphenylenediamine compounds are frequent sensitizers.

To determine the possible allergic sensitization of new cosmetic and pharmaceutical compounds, the patch tests at the present time are being empirically used for this purpose. The proposed product when utilized may cause dermatitis venenata due to primary sensitization or allergic manifestations. Acids and alkalis when used in strong concentrations as in the chemical, brewing and cleaning industry, very frequently produce damaging effects upon the skin; this reaction is classified as a primary irritant. However, when this same agent is evaluated it is reduced in its testing concentration from one-tenth to one-fiftieth of the original strength, and subsequently if a reaction occurs upon the skin then it is classified as an allergen. When testing household products as turpentine, nickel sulfate, DDT, pyrethrium powder, ammonium fluoride, usually a 1 to 5 percent dilution is utilized to reduce it from the class of a primary irritant.

The procedure used in patch testing is to select the suspected allergen, new ingredient, pharmaceutical, or cosmetic product to be tested. This material is utilized in proper dilution or dispersed in an innocuous aqueous solution or petrolatum, and then placed upon the skin. The tested product is covered with a piece of gauze which is kept in direct contract with the skin with adhesive, or scotch tape. The test is left in contact with the epidermis for a period of 48 to 72 hours. The original test patch areas are read and the reaction noted. This is identified as the prophetic patch test.

Occasionally, sensitization does not take place immediately. The test materials are then reapplied to the skin, in similar dilutions, in different areas 4 weeks after the initial test to determine whether an altered reactivity of the natural factors of the skin have occurred. The usual period for normal skin to demonstrate sensitivity to an allergen varies from a minimum of about 2 weeks to years.

However, in our testing of cosmetics, we have added the consumer usage test. This test consists of utilization of the cosmetic effect by the patient or consumer in the area for which it was originally intended. For instance, lipstick would be used on the lips, nail polish on the nails, hair dye and shampoo upon the hair and scalp. In order to determine whether sensitization will take place, the control patients are advised to use the preparation daily for a definite prearranged time. In this manner, a new preparation can be more accurately and readily screened as to its epidermal sensitization, when the prophetic and repatch tests are utilized in combination with the consumer usage tests.

Occasionally the untoward effects may not present themselves after original testing, and may appear several weeks or months after initial

use of a product. To cite an example, we are all familiar with the allergic toxic effects of the undercoat nail preparation which was used to cause a more lasting effect of the nail polish. This preparation consists of a rubber and resin solution and methyl ethyl ketone solvent.

Dr. Charles Rein and Dr. James Rogin in the June 1950 issue of the Archives of Dermatology and Syphilology described the allergic eczematous reactions of the nail bed due to "undercoats." The clinical features presented were discoloration and subungual hyperkeratosis, onycholysis of the distal portion of the nails and paraonychia with edema, erythema and scaling of the fingertips. Associated with the afore-mentioned symptoms were pain, tenderness, and paresthesia.

Sulzberger and Mitchell believe that the previously mentioned condition was an allergic reaction whereas Winston and Sutton believed the effect to be due to methyl ethyl ketone solvent.

Sharlit stated that the condition was probably due to a contact allergen.

We are also of the opinion that it is an acquired allergic sensitivity especially since this dermatitis did not occur until after several months of usage. These reactions, although they were small in number, considering the many people who used the undercoat nail polish, were severe and resulted in pain and disability.

I have been informed that when the patch tests of the undercoat were performed on 200 or more patients, the amount of sensitization that appeared was almost minimal to the individual components and to the final product. However, I am unprepared to state whether or not this preparation was applied to the nails previous to the application of nail polish. We can readily observe that individual chemical components of a cosmetic preparation may in themselves be innocuous or not cause sensitization. However, when they are combined, the final product may act as a potential allergen sensitizer. We must not lose sight of the possible toxic chemical combinations of two individual substances that are used simultaneously as the combination of the undercoat protector and the nail policy. We also believe the hair dye and the cold permanent wave when used in conjunction with each other.

In a preliminary hearing of this committee on the Pacific Coast, it has been called to my attention that one of the experts testified that there are about 135 different items used in the cosmetic industry which can be classified as known sensitizers.

Dr. Klarman at the 1951 annual meeting of the Society of Cosmetic Chemists suggested that this list was incorrectly quoted. I am in accord with his statement, in that I believe that the list contains drugs which on rare occasions are known to cause an allergenic reaction in patients and consumer. However, we do not consider these primary sensitizers when used in the majority of cosmetics sold today. We do recognize that these occasional allergens may cause a skin irritation especially in patients who have an allergic background, namely, asthma, hay fever, and atopic dermatitis.

In the practice of dermatology we see very frequently chronic eczematoid reactions of the skin of the hands of women, who during the past few months have been engaged in more than the normal amount of washing and rinsing of babies' clothing and wearing ap-

parel. These patients are hypersensitive to ordinary washing with household soap and water, which act as skin irritants. We surely realize that the skin of the hands and body are subjected to millions of applications of soap and water daily, and still the percentage of abnormal reactions is almost minimal. The same analogy applies to previously mentioned sensitizers as discussed in the Pacific Coast hearings.

I have attempted to show that the majority of cosmetic formulations that may cause skin sensitization are basically noninjurious. If a new cosmetic contains chemical agents or combinations of agents which may have an untoward effect upon the skin or other appendages of the body, then it should be subjected to pretesting procedure, before it is allowed to be used by the consumer and sold over the counter.

The pretesting procedure at the present time is empirical, and I believe certain rules and regulations should be formulated to determine the constituents of a new cosmetic without the production of toxic consequences. The majority of dermatological and cosmetic consultants recommend about 200 patch tests as the minimum for new cosmetic preparations. We are in accord with this number.

In addition, we also believe that the consumer usage tests should also be added.

The individual ingredients and the finished preparation should be patch tested and then in a 2- to 4-week period repatch testing should be performed to rule out the potential sensitization. In conjunction with this procedure, I believe the consumer testing should also be conducted at the same time. Namely, the continued use of the preparation on that part of the body for which it has been proposed. Animal testing occasionally is advised to determine the toxic properties of a new preparation which has not been utilized on human skin previously.

I would also suggest that to minimize infrequent occurrence of potentially toxic reactions following the use of new cosmetic preparations, a qualified dermatologist and allergist should be utilized as a consultant by cosmetic manufacturers and the Government. The dermatologist besides being a qualified specialist in the field of dermatology, should have expert knowledge of allergy, pharmacology, and be able to facilitate practical application of a cosmetic product from its inception in the laboratory to its sale in the retail outlet.

Dr. Erwin D. Cyan at the 1951 spring meeting of the Society of Cosmetic Chemists, elaborated on the usage of the consumer acceptance test. We have modified his original plan and suggestions by the consumer usage evaluation, specifically the cosmetic to be tested, is used on the area of the body for which it was originally intended.

As previously mentioned, cosmetics to be tested should be used on the areas of the body for which they are originally intended.

Therefore, we eliminate any doubt as to whether it has toxic properties in the selected use areas. We must not forget that occasionally patients have demonstrated allergic manifestation to a cosmetic, as for instance nail polish, and still when a patch test of nail polish is applied in an unrelated skin area, the result is negative. This occurs with infrequency and therefore can be discounted.

It may be advisable for the cosmetic industry and the Federal Government to publish a manual indicating the reactions to known allergens and sensitizers so that their frequent use in cosmetic preparations

may be discouraged in the future. An official publication may be desirable.

I must emphasize when a pharmaceutical or cosmetic preparation has been submitted to my office and laboratory for clinical evaluation, and any severe untoward effects have been observed during the clinical study and screening of this product, that the manufacturers have been only too cooperative in insisting that this prospective product be discarded as a potential merchandise product.

In conclusion, I hold that since the pharmaceutical and cosmetic manufacturers are interested in net sales and profits, without discomfort or hazard to the consumer, and unwarranted publicity that impeaches the reputation of the cosmetic manufacturer, that there should be no difficulty in the formulation of new legislation or amendment to existing adequate laws.

This legislation and recommendations should emanate after an unbiased and cooperative conference between representatives of the manufacturers, the Government and impartial experts, thus insuring adequate proposals without undue hardship to the participating parties.

As in all scientific domains in which rapid progress is being made, certain differences of opinion will present themselves, and ultimately, there should be a general agreement on the proposed details, and with complete satisfactory acceptance by all the parties concerned.

Mr. KLEINFELD. Dr. Lubowe, on page 10 of your statement you say that we can readily observe that individual chemical components of a cosmetic preparation may in themselves be innocuous or may not cause sensitization. However, when they are combined, the final product may act as a potential allergen.

In other words, I think you are saying, if I am correct, that you may have two substances, each of which, by itself, may be entirely innocuous, or each of which, by itself, may have no allergenic effects; is that correct?

Dr. LUBOWE. Yes.

Mr. KLEINFELD. But that when you combine the two you have a new problem?

Dr. LUBOWE. That is correct.

Mr. KLEINFELD. The combination itself may cause some allergic reactions or some direct damage; is that correct?

Dr. LUBOWE. Yes; due to the fact that you are probably producing a new chemical compound or changing the *p*H of the preparation used, toxic effects may be produced.

Mr. KLEINFELD. That is why you say that we must not lose sight of the possible toxic chemical combinations of two individual substances that are used simultaneously, as for example the combination of the undercoat protector and the nail polish?

Dr. LUBOWE. Correct.

Mr. KLEINFELD. So that if a client of yours was going to put out an undercoat for nail polish you would want that tested with the nail polish itself; is that correct?

Dr. LUBOWE. Yes; that is exactly it. The consumer clinical usage test would duplicate the exact conditions under which the cosmetic preparations would be used in the beauty shop or the household.

Mr. KLEINFELD. That would be the safe thing to do?

Dr. LUBOWE. Yes.

Mr. KLEINFELD. Doctor, suppose you had a wetting agent which, in itself, would not cause any damage even if inserted directly into the eye, and thus if used in a shampoo which might get into the eye would not cause any direct damage. Suppose you also had a quaternary compound which in itself, if put directly into the eye or used in the shampoo, would not cause any direct damage. Might you have a different problem if you put the two together?

Dr. LUBOWE. Yes. There is a great possibility that some untoward chemical action may occur which may not be innocuous to the mucous membrane or conjunctiva of the eyeball.

Mr. KLEINFELD. Apparently it is your definite opinion that the fact the ingredients of a cosmetic may have been tested quite sufficiently does not at all relieve the manufacturer from making the kind of tests you mentioned upon the finished product?

Dr. LUBOWE. Yes, and I am in accord with that.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Hedrick.

Dr. HEDRICK. Do you believe that atomic energy will be used frequently in the treatment of skin diseases in the future?

Dr. LUBOWE. Previously mention was made of radioactive substance. At the present time thorium X, which is an alpha compound is now being used in dermatological preparations, and in a large number of cases seems to be effective in its accepted therapeutic indications. In all probability, we think it will be used with greater frequency if found to be further effective and nontoxic.

Dr. HEDRICK. How about in the treatment of cancer?

Dr. LUBOWE. Basically my field is dermatology. However, we do know that the isotopes of the cobalt and gold compounds are now being used in the treatment of cancer and the detection of cancer. And although the reports are not conclusive, there is a feeling that they will be beneficial.

Dr. HEDRICK. I believe that is all.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. Dr. Lubowe, in your statement before me here, you make the point that if we can assure the public we should have no difficulty in arriving at proper amendments.

Dr. LUBOWE. Yes; I believe so.

Mr. HORAN. Specifically what did you have in mind; speaking as an individual?

Dr. LUBOWE. Well, I believe that there are a number of cosmetics that are now being used with a great deal of caution by the consumer, because of the fact that they do not have approval of the Federal Government or medical profession, and if this approval was offered some of this fear would be dispensed, and probably greater usage of cosmetics would result—just to mention one particularly, the hormone preparations.

Mr. HORAN. How do we arrive at the clearance you mention under the existing procedures?

Dr. LUBOWE. You asked one of the previous witnesses what part the United States Public Health Service would play. I think specifically we are all interested in private enterprise, and I think that all evaluation should still be in the hands of the cosmetic manufacturer and the private individual. However, there is possibility that it can be

worked in conjunction with the function of the National Research Council today, which is a governmental agency. In the testing of new projects and new compounds they employ private investigators, and then the results are brought back to the National Research Council; and then in turn these reports are incorporated and issued by the National Research Council. It offers, and institutes grants to the various universities and private investigators. I think there is a possibility of introducing a similar agency with governmental and private researcher cooperation.

Mr. HORAN. Here is the problem we are up against: I believe in private enterprise myself; but, of course, you know we hold them under suspicion at times, and that is the problem we have, to find an agency that can give clearance to the ethical manufacturer. We need to protect him and that is what we want to do. But we have got to find some way to credit or to certify the findings of his own researcher, or we have to find what might be an unbiased body to make the same findings and certify them so that we can give the green light to the private enterpriser. That is the problem as I see it, and I think your testimony would indicate that you more or less think in the same line. Is that not true?

Dr. LUBOWE. Yes. I believe that basically all the testing and clinical reports should be done by private industry with a control if a Federal agency believes it is essential, as we are now doing with the new pharmaceuticals. I think the same type of a set-up would be an agreeable one.

Mr. HORAN. Thank you.

The CHAIRMAN. That is all. Thank you, Doctor.

Mr. KLEINFELD. Is Dr. Grolnick here?

Dr. GROLNICK. Yes.

The CHAIRMAN. Your name and address, Doctor?

Dr. GROLNICK. Max Grolnick, 555 Ocean Avenue, Brooklyn, N. Y.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF MAX GROLNICK, M. D., BROOKLYN, N. Y.

Mr. KLEINFELD. Dr. Grolnick, you have the degree of doctor of medicine?

Dr. GROLNICK. That is right, sir.

Mr. KLEINFELD. Where did you obtain that degree?

Dr. GROLNICK. The Long Island College of Medicine.

Mr. KLEINFELD. What year?

Dr. GROLNICK. 1926.

Mr. KLEINFELD. And you have practiced medicine since then?

Dr. GROLNICK. That is correct.

Mr. KLEINFELD. What is your special field?

Dr. GROLNICK. Allergy. I am an allergist.

Mr. KLEINFELD. And how long have you specialized in the field of allergy?

Mr. GROLNICK. Since 1929.

Mr. KLEINFELD. Of what societies are you a member?

Dr. GROLNICK. I am a fellow of the American Academy of Allergy, a fellow of the American College of Allergists a member of the New York Allergy Society, and a recent president of same.

Mr. KLEINFELD. Are you associated with any hospitals?

Dr. GROLNICK. I am.

Mr. KLEINFELD. Which hospitals?

Dr. GROLNICK. I am associate attending physician in allergy at the Brooklyn Jewish Hospital and associate attending physician in medicine and chief of allergy division Miamonides Hospital in Brooklyn. I am also instructor in dermatology, College of Medicine, University of State of New York.

Mr. KLEINFELD. Will you please read your statement.

Dr. GROLNICK. Some cosmetics, particularly hair dye and wave preparations may cause local or general allergic reactions in the skin, and in the nasal and bronchial mucus membranes. The distress produced may vary from mild to serious, from local to generalized, and may rarely lead to fatality, from direct or indirect causes. The present law give inadequate protection from such recommendations as label warnings, preapplication patch-testing, and careful observance of instructions for use. This actually applies to certain known hazardous chemicals, such as the amine or aniline type of synthetic dyes, some metallic dyes, some hair wave chemicals, and others. Even these inadequate precautions presuppose an intelligent interpretation by the user or by the beauty parlor operator. Any change in Federal regulations should consider the following:

Eliminate such ambiguities which permit the use of dye on the scalp, but not around the eyes, which permit use on the skin but not on the lips or mucus surfaces, and even exempt certain dyes from the color certification requirements of the FDC Act.

A preuse patch test self-applied by the user of a cosmetic, or by a beauty parlor operator is obviously inadequate, and presupposes that it will be carried out, and if so, that the result will be interpreted properly. Even the trained specialist has difficulty in interpreting these tests at times.

In permitting certain toxic or sensitizing (allergenic) chemicals to remain on the market, a proper evaluation of what constitutes a reasonable risk must be reached, i. e., how many people can be harmed before a chemical is to be branded as objectionable.

New cosmetic chemicals, just like drugs, should be subjected to proper study by experienced persons to determine the potential sensitizing (allergenic) capacities or hazard, prior to their release for use by the public.

At present there is no accepted standard procedure for such studies, and an organized endeavor seeking the cooperation of such bodies as the Food and Drug Administration, the United States Public Health Service, the Cosmetic Committee of the American Medical Association, the Research Council of the American Academy of Allergy, and of other bodies such as the American College of Allergists and the American Academy of Dermatology, should be undertaken.

I trust that the above expressed views will be of assistance to you and your committee.

Mr. KLEINFELD. Dr. Grolnick, in item No. 2 in your statement you say that—

A preuse patch test self-applied by the user of a cosmetic or by a beauty-parlor operator is obviously inadequate, and presupposes that it will be carried out, and if so, that the result will be interpreted properly.

In other words, you don't believe that the ordinary user of a cosmetic is qualified to apply, or to judge correctly the results of, a patch test; is that correct?

Dr. GROLNICK. That is right.

Mr. KLEINFELD. And as an allergist, do you think the ordinary beauty-shop operator is qualified to judge the results of a patch test?

Dr. GROLNICK. I don't feel so.

Mr. KLEINFELD. You say also, "Even the trained specialist has difficulty in interpreting these tests at times." Is that right?

Dr. GROLNICK. That is right. The difference between primary irritation by a chemical and a reaction indicating a true allergic response of the skin may be difficult to distinguish by the untrained person.

I have an interesting statement in an English text on modern cosmeticology which pertains to that, and I am prepared to read it for you if you wish me to quote from it.

Mr. KLEINFELD. I wish you would. What is the name of the publication?

Dr. GROLNICK. It is a book by Ralph G. Harry, who is a fellow of the Royal Institute of Chemistry and the text is Modern Cosmeticology published by the Chemical Publicity Co. in Brooklyn. The author is head of the cosmetic department of Beecham Research Laboratories. I got the text from the medical library in Brooklyn. He is discussing patch tests, and states:

> Even though the actual procedure is simple, they should not be carried out by beauty-parlor operators, as in unskilled hands very disastrous results may accrue. On the manufacturing side these tests are often conducted by qualified specialists in the biochemistry of skin, who are intimately acquainted with the chemical constitution of the substance being tested, its pH titrable alkalinity or acidity, toxicity, and its chemical and structural relationship to substances already known to be irritant. No valid objection exists to patch tests by such investigators. Apart from such specialized research work, however, patch testing is definitely the province of the dermatologist to whom all such tests should be referred.

I might supplement this by stating that with unknown chemicals, particularly, it is a known fact that the application of a chemical which may be allergenic—and, of course, it may be unknown at the time it is being applied that it is allergenic—may sensitize the entire body surface by a single patch test. Some chemicals can be that potent.

Mr. KLEINFELD. Doctor, in point 3 of your statement you say:

> In permitting certain toxic or sensitizing allergenic chemicals to remain on the market, a proper evaluation of what constitutes a reasonable risk must be reached, that is, how many people can be harmed before a chemical is to be branded as objectionable.

Who do you think should make that evaluation?

Dr. GROLNICK. There are such private bodies as those that I mentioned—the various dermatological and allergy societies—and there are the governmental organizations. I think that an organized effort on the part of all these groups should ascertain that evaluation, and not certain local groups. There is a committee on cosmetics that was organized under the aegis of the American Medical Association just a few years ago. They are doing a good job I am sure. But I feel it is a local group. I believe there should be regional divisions of that particular committee or similar committees throughout the country.

Mr. HORAN. Mr. Chairman, I think if counsel will permit, in point 5 Dr. Grolnick tries to get at a procedure for an answer. I think your answer is in 5.

Dr. GROLNICK. Yes, that is correct.

Mr. HORAN. Your answer in 5 suggests some way to bring all of these forces together that could supply the answer or the proper level. He makes that point. I think it is very valuable.

Dr. GROLNICK. In 5 I was talking about adopting a standard prerelease testing procedure. There is no accepted standard procedure. And I referred to that particular aspect of the work in suggesting a joint endeavor. But, of course, the arrival at some proper evaluation of a hazardous drug could be reached in more or less in the same fashion.

Mr. HORAN. If you will permit me, I think the very crux of what we may do as a committee of Congress will result in this: We will propose legislation. The legislation, if it is enacted, will enable some part of our Federal Government to take action and do these things you are suggesting.

Much of the things that you as a doctor, working in the field of allergy and so forth, may experience in the future will not be legislative, it will be regulatory. You see we write basic legislation but the administration sets up the regulations under which you will function. It will not be the law you will be under, it will be the regulations of bureaucracy. So let's find out who we want to regulate us.

I think you are hitting awfully close to the head of the nail here in No. 5. That's what we ought to be getting at in my opinion, in answer to the question that Mr. Kleinfeld asked you, and that is the reason I interrupted Mr. Kleinfeld.

We are getting down to the crux of the thing here in my opinion, and you have made an answer that does appeal to me.

Dr. GROLNICK. If I may be permitted to elaborate on that fifth point before the close of this session, I would appreciate it, because I am particularly interested in that point No. 5, having had some direct experience in that aspect of the study.

Mr. KLEINFELD. You say you want to elaborate?

Dr. GROLNICK. Should I do it now?

Mr. KLEINFELD. Yes, surely.

Dr. GROLNICK. In reference to the procedures for determining the potential skin sensitizing hazard or capacity of a chemical. It is generally known that the accepted procedure is to apply a small amount of the drug or chemical under study as a patch test for a period ranging from 2 to 5 days, and then a re-application of that particular chemical 2 weeks later. That 2-week interval apparently suggests the incubation period which is necessary to elapse before the general human body is sensitized to that particular substance.

That procedure, as I assume you know, is suggested by Dr. Louis Schwartz of the Public Health Service, and it has been generally carried out.

Now it is my impression, after having done a fair amount of experimental studies in the human subject—not in the experimental animal—that several procedures using the original premise should be developed, and that no one procedure is adequate for the study of one particular chemical, because all cosmetics or drugs to be used locally are not used in the same manner. Some of them are used in a local area, some of them are used all over the body. Some of them are used more freely than others. I feel that several procedures ought

to be developed, taking in the various theoretical concepts and experiences of many investigators. That is why I suggest some organized endeavor by the various groups, because fundamentally one has to put great reliance on this first step. If the product passes this test then it can generally be released.

I feel that, in addition, there should be a usage test besides these patch-test procedures. I think the techniques for appropriate test procedures can be developed.

I know that the Food and Drug Administration is developing a procedure which will probably be reported on very shortly. In my own right I have tried to use a procedure which is a slight modification of the general Schwartz procedure and has experimental support. I am sure others have other suggestions.

I feel too the usage test is important. Let me say, for example, there could be a continuous usage over a period of at least 30 days, which we consider as the incubation area period, and then observation for several weeks after that. Then, as has been suggested by others, limited field sales and use under no particular direction, and all complaints coming in therefrom to reach the original source of sales or some other body. I know that Schwartz has recommended some such procedure.

And then finally the report of untoward reactions from such a field study should be analyzed by various regional boards organized by private medicine and Federal agencies.

Mr. KLEINFELD. From the viewpoint of the allergist, Doctor, are you interested in the reactions caused by soaps?

Dr. GROLNICK. Yes.

Mr. KLEINFELD. In your opinion, may the same problems be presented with respect to soaps as are presented by the use of other cosmetics?

Dr. GROLNICK. It is not nearly as distressing or hazardous, of course, as some of the other problems, particularly the problem which pertains to the use of hair dyes—aniline or amine type of hair dye.

Mr. KLEINFELD. Have you noticed in your practice any particular adverse reaction caused to persons by the use of a particular soap or soaps?

Dr. GROLNICK. From time to time you get a sporadic case, but they are never very severe.

Mr. KLEINFELD. Doctor, in point 3 of your statement, you discuss a proper evaluation of what constitutes a reasonable risk. Do you think that evaluation should be made by each individual manufacturer or distributor of a cosmetic?

Dr. GROLNICK. I wonder if I made myself clear. After a preparation has been on the market for a number of years, and numerous cases have been reported of either localized or generalized dermatitis or possibly mucous membrane manifestations, then, how many people have to be involved in this particular injury before the product is limited or removed?

Mr. KLEINFELD. Here is what I am trying to get your opinion on: If a cosmetic manufacturer wants to put out something new he has to make certain tests as you suggest; is that correct?

Dr. GROLNICK. That is correct.

Mr. KLEINFELD. And he has to decide for himself whether a product may hurt somebody or hurt a number of people, and he must make

that decision on the basis of the tests he has carried out. Sometimes the tests may be quite adequate or sometimes, I suppose, they may be inadequate. Do you believe he should be permitted to make the final decision as to whether the tests he has made have been entirely adequate?

Dr. GROLNICK. I think that might depend on how wide a use the particular cosmetic or drug would be given.

Mr. KLEINFELD. Suppose it is to be given rather wide use, to be used by hundreds of thousands, perhaps several millions of people. What would you require from a manufacturer of a new product before it was sold commercially to so many people? If you have an opinion on it?

Dr. GROLNICK. Yes; I think it ought to be gone over by some organized group comprising both private medicine and some governmental agency, and having representatives from both general groups.

Mr. KLEINFELD. That is all.

Dr. GROLNICK. Mr. Kleinfeld, I don't know whether the question of hazards of cosmetics from the standpoint of mucous membrane sensitivity has been brought out. From the standpoint of the allergist I am interested in that, and possibly the dermatologist doesn't call attention to it.

The CHAIRMAN. We would like to have your opinion on that.

Dr. GROLNICK. We know certain foods and inhalant substances, and certain chemicals which enter the body by the usual routes, may cause mucous membrane symptoms involving the upper and the lower respiratory tract, producing bronchial asthma. And one of the most severe type of reactions that may occur, though fortunately infrequently, is that which follows the ingestion of aspirin.

I am just bringing this up as an example that certain chemicals introduced in the body can produce both nasal allergy and bronchial asthma. And there are chemicals incorporated in certain cosmetic preparations which may from time to time produce such symptoms, too. Fortunately, there aren't very many of them but there are a few that might be called attention to.

The CHAIRMAN. Patients would hardly associate that condition with the use of cosmetics.

Dr. GROLNICK. That is correct.

The CHAIRMAN. So it might be more numerous than brought to our attention.

Dr. GROLNICK. That is correct. It is up to the vigilance of the allergist or the attending physician to realize this particular fact.

The CHAIRMAN. And that is so with all products—drugs and cosmetics and chemicals and food and so forth?

Dr. GROLNICK. Yes.

The CHAIRMAN. It is almost impossible to get an accurate survey as to what conditions might be caused; is that so?

Dr. GROLNICK. Yes, that is correct.

The CHAIRMAN. I see.

Dr. GROLNICK. For example, paraphenylenediamine, which is used in hair dyes, is a cause of bronchial asthma in workers among fur dyers and those that handle the crude drugs in the manufacture of the chemicals. It is reasonable to assume, although it is not often called to our attention, that even its use in cosmetic preparations may indirectly have some bearing on the production of mucous membrane symptoms. Also such preparations as orris root, flaxseed, and the

various natural gums which are frequently used in cosmetics may produce mucous membrane symptoms.

The CHAIRMAN. Dr. Hedrick.

Dr. HEDRICK. Doctor, do you believe that a manufacturer who brings out a new product and wants to put it on the market for sale, should bear all expense and costs for determining the value of that drug, as to whether it is harmless or detrimental to the human being?

Dr. GROLNICK. By whom?

Dr. HEDRICK. By the company which makes the product. In other words, it should not be the cost of the Government to determine whether that product is safe or not. The manufacturer in my opinion should pay the cost of determining whether it is harmless or detrimental to the human being.

Dr. GROLNICK. I should think so. I do not know that I am qualified to answer that question. But as an individual I would think that is reasonable.

Dr. HEDRICK. That is all.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. The question I want to ask Dr. Grolnick—and I am intrigued by point No. 5 because I would like to see something as you suggest carried out myself—are you a member of the AMA's cosmetic committee?

Dr. GROLNICK. No, sir.

Mr. HORAN. Do you know why the American Medical Association thought it wise to set up such a committee?

Dr. GROLNICK. Well, I think it was a voluntary regulatory attempt.

Mr. HORAN. Yes; it was.

Dr. GROLNICK. It was probably instituted because of the numerous reports of cosmetic dermatitis within the past decade or longer, coming as epidemics of this very distressing condition. Somewhere around 1933 "Lash-Lure" which contained paraphenylenediamine dye used to dye eyelashes, produced a series of cases of conjunctivitis and cataract and actual blindness, and I think in that series there was even one reported fatality. And then, of course, there were the not-infrequent cases of dermatitis due to hair dyes either on the face or generalized. It may start out as a local reaction and develop into a more generalized one. So I think the organization of the cosmetic commission was motivated by these sporadic or epidemic appearances of dermatitis due to cosmetics.

Mr. HORAN. You would agree then it was a constructive attempt to give assurance to the consumer and protection to the ethical manufacturer?

Dr. GROLNICK. Yes; very definitely.

Mr. HORAN. But it is voluntary?

Dr. GROLNICK. I believe it is.

Mr. HORAN. That is true. We have had some manufacturers who have used that service and others that did not.

The effect of further action in that field, or the possible effect of carrying out your suggestion under point 5, might make it mandatory, probably would make it mandatory on all manufacturers to use the service. Do you think that that would be advisable?

Dr. GROLNICK. Yes, sir. That is the point I care to bring out in that fifth item.

Mr. HORAN. That is the point I wanted to get your agreement on. Thank you.

The CHAIRMAN. There is a certain danger in that, is there not, Doctor—regimentation and regulation by such groups who are not directly responsible to anyone?

Dr. GROLNICK. I do not think so.

The CHAIRMAN. You don't think so?

Mr. HORAN. I don't either. If it is properly set up.

The CHAIRMAN. If everything is properly done we would have little or no trouble. It is the possible abuse of these things.

Mr. HORAN. The witness and I both want it done right, I think.

The CHAIRMAN. I think everyone wants it done right, but there is the question of how are you going to control these things. You may get one man who would operate the thing to the satisfaction of everyone, and then somebody else might just set himself up as a czar.

We have to look at many sides of this, Doctor. It is not an easy thing even to propose legislation, because there are many dangers.

As I pointed out here yesterday, I believe, there is a possibility of an outside group coming in and charging us with creating a monopoly.

Mr. HORAN. May I give a practical example of this? I come from the State of Washington. You cannot ship an apple out of the State of Washington without the agreement of the Food and Drug Administration. We sell a lot of apples in the city of New York. And that should be assurance to the consumer.

We do not feel that we are regimented, we feel that is part of our security, that we are able, by the way we operate out there, to give assurance to the consumer. And that is what your ethical manufacturer wants.

If this thing is set up properly, it does not necessarily mean regimentation, and it does not necessarily mean anybody is going to be bearing down.

But I personally—and I have had some experience in this field—not in cosmetics—and I know it has to exist, and Dr. Grolnick, I think, knows there is a need for something like this or he would not have made this suggestion. And whether we like it or not, we have either got to say it is not necessary or we ought to have it. That is the decision in my opinion that we must make.

The CHAIRMAN. Off the record.

(Discussion off the record.)

Mr. HORAN. Incidentally, Dr. Grolnick, your testimony was very good. We appreciate your appearance.

Dr. GROLNICK. Thank you.

The CHAIRMAN. The next witness.

Mr. KLEINFELD. Mr. Soroko.

The CHAIRMAN. Your name and address?

Mr. SOROKO. Mark D. Soroko, 745 Fifth Avenue.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed.

TESTIMONY OF MARK D. SOROKO, GENERAL SERVICE MANAGER, REVLON PRODUCTS CORP., NEW YORK CITY

Mr. KLEINFELD. You are the general service manager for Revlon Products Corp., Mr. Soroko?

Mr. SOROKO. I am, sir.

Mr. KLEINFELD. As general service manager, what are your duties?

Mr. SOROKO. Well, I assist the officers of the corporation and act as liaison between them and the departmental heads.

Mr. KLEINFELD. Pursuant to the request of this committee, there is attached to your statement a list of the products manufactured and distributed by Revlon?

Mr. SOROKO. There is.

Mr. KLEINFELD. Does that list include all the products Revlon makes or distributes?

Mr. SOROKO. That is right.

Mr. KLEINFELD. And there is attached to your statement a list of the raw materials used in your products?

Mr. SOROKO. That is right, sir.

Mr. KLEINFELD. Is that a complete list of all the ingredients which are used by you?

Mr. SOROKO. To the best of my knowledge.

Mr. KLEINFELD. Please read your statement.

Mr. SOROKO. Revlon Products Corp. has been in the business of manufacturing and distributing cosmetics for 20 years. Our products and ingredients are listed in the appended tables I and II.

It is our policy to purchase raw materials only from the most reliable sources equipped to give the best control of purity and uniformity.

Every shipment of raw material received is given a receiving number and each package of each shipment is sampled and sent to the chemical control laboratory, where it is tested and either accepted or rejected by chemists on the basis of specifications which we have set up. These specifications are USP or TGO or equivalent. The laboratory keeps a file of the tests made on each shipment and retains a sample of each after the tests are completed.

Each package of raw material is marked with the receiving number when it arrives at the plant, but no package may be used in the plant until it has been released by the chemical control laboratory.

In the manufacturing department, as each batch of a product is made, a manufacturing record is filled out which shows (*a*) the exact amounts of each ingredient, and (*b*) the analysis number of each ingredient.

The completed batch of each product is checked by the laboratory and a sample of the finished batch is retained.

We exert painstaking measures to ensure the production of good cosmetics. We use outstanding dematologists as consultants. Before marketing, both the raw materials and the finished products manufactured by us are subjected to rigid tests. The products we distribute, but not manufactured by us, are subjected to equally stringent tests.

Extensive patch testing is done under the direct supervision of a competent dermatologist, in the case of each individual produce. If the results of this patch testing are satisfactory, actual-use tests are then conducted on a number of people, ranging from 400 to 600, over a period of 90 days, after which field tests are conducted. If all of these tests are satisfactory, the product is then marketed.

We feel quite confident that under our system of checks and tests, primary irritants never find their way into our products. However, because no two human beings are entirely alike, there will always be the isolated individual factor of allergy, which goes far beyond the scope of cosmetics.

In answer to your request for our views or recommendations, we feel generally that an impartial body of competent authorities could be designated to consider and pass upon all cosmetics, in the interests of the public health, under a pattern to be worked out.

(The table submitted by Mr. Soroko listing the ingredients is in the files of the committee.)

Mr. SOROKO. Mr. Chairman, I would like to add something which will take another brief minute or two by way of an addition to the last paragraph of my statement.

The CHAIRMAN. Go right ahead.

Mr. SOROKO. May I have that permission?

The CHAIRMAN. Yes.

Mr. SOROKO. As the committee knows, and counsel, I have been an interested observer at these hearings, here in New York, since they commenced last week. I came prepared to stay for an hour or two, and my interest was so stimulated that I remained constantly throughout the entire hearings.

The purpose of this supplementary statement is to comment on certain aspects of the testimony already adduced, which from our experience require classification.

Our firm has a sincere desire to assist this committee in its objective, which is to determine whether amendatory legislation to current cosmetic regulations is necessary and if so what that should be.

We have already indicated in our principal statement that for the full protection of the public health a monitor in the form of a body such as, if not in fact, the committee on cosmetics of the American Medical Association might be helpful. In this connection, we should like to point out that the AMA committee on cosmetics would not constitute a group within an industry regulating the entire industry. This committee obviously is not a part of the cosmetic industry. We mention this point because of the fear previously expressed that this might be a dangerous precedent to establish in the American business world.

Another point which we feel needs clarification is the matter of fairness to the small firms in the cosmetic industry. Mr. Delaney, the chairman of this committee, has very pertinently expressed concern about the possibility of legislating the small firm out of existence by imposing expensive product-testing requirements. It is very important to realize that the AMA committee on cosmetics makes absolutely no charge for the safe-use testing of cosmetic products submitted to it. Perhaps this is an area where education and enlightenment, which one of the previous witnesses so earnestly championed, would be advantageous.

Our firm, as I am sure all other enlightened firms in this industry, need have no fear of any new intelligent legislation. We feel that if mistakes are made in the legislative process, the very force of the error will require congressional correction. A historic example of this was in the social legislation of the National Labor Relations Act and the subsequent passage of the Taft-Hartley Act.

To a very large extent, the decision of this committee as to whether further legislation is needed will be dependent upon the testimony of the medical specialists, especially in the field of dermatology. I confess that I have found the testimony of some of these eminent physicians just a little confusing. While I am no dermatologist, and

hold no degrees in any of the sciences, my close acquaintanceship with some of the leading people in that field and the real practical problems presented in the marketing of our products, leads me to the conclusion that there are two basic and distinguishable aspects in the etiology of skin diseases. One is the primary irritant type, and the other the allergenic type.

It is quite obvious that no type of testing can guarantee a complete absence of allergenic symptoms arising from the use of cosmetics. The best that any tests known to medical authorities can do is to eliminate primary irritants and sensitizers, before marketing. In this connection, it is interesting to observe that the Federal regulatory authorities have prohibited various cosmetic firms from advertising certain of their cosmetic products as being nonallergenic.

I think it is important to emphasize something which practically everyone knows. This is, that we are all allergic to something or other in the course of our lives. I am sure the percentage of people who cannot take orange juice is no smaller than the percentage of people who are allergic to any given cosmetic.

We trust that this statement will be helpful to the committee.

The CHAIRMAN. Now, since you qualify as an expert observer here and you have been here for 3 or 4 days—and I am leading with my chin—what is your reaction on the manner in which these hearings have been conducted?

Mr. SOROKO. I think the committee has bent backward to try to help the cosmetic industry and the public.

The CHAIRMAN. We appreciate that. And, as I say, I am bound by your answer because I called you as my witness. [Laughter.]

Mr. Horan just observed that many of them are allergic to regulations. [Laughter.]

I think that is so, too.

Mr. Kleinfeld?

Mr. KLEINFELD. Does the Revlon Co. submit its products to the committee on cosmetics of the American Medical Association?

Mr. SOROKO. We do. We have never had any of our products refused approval.

Mr. KLEINFELD. Do you submit all your products?

Mr. SOROKO. All our products.

Mr. KLEINFELD. You do not have any technical training, do you?

Mr. SOROKO. No, sir.

Mr. KLEINFELD. You point out there is a difference, which I think the committee well realizes, between direct primary irritation or injury and allergic consequences. Is that right?

Mr. SOROKO. That is correct. In isolated instances, those that appear in isolated instances.

Mr. KLEINFELD. But your company, in making the tests which it conducts and has conducted, tries to take both types of damage into consideration?

Mr. SOROKO. Definitely so.

Mr. KLEINFELD. In other words, if your patch tests and your use tests show some reaction which you might denominate as being an allergic reaction to a group of people which your doctor would think was a little large, you would not put the product out, would you?

Mr. SOROKO. Definitely not.

Mr. KLEINFELD. And why do you take all these precautions?

Mr. SOROKO. Well, we are quite jealous of our reputation. We have built this company up from its very beginning, which was nothing, and we feel we owe it to our public, to the consumers, to do the most that medical science has been able to advise us to do to prevent any unusual or any predictable injury or reaction.

Mr. KLEINFELD. Do you think the public is entitled to such protection?

Mr. SOROKO. They certainly are.

Mr. KLEINFELD. Do you believe that your competitors should observe the same general precautions?

Mr. SOROKO. That is a leading question.

Mr. KLEINFELD. Right.

Mr. SOROKO. And I would like—I would say "Yes" if you will permit me to amplify it.

Mr. KLEINFELD. Surely.

Mr. SOROKO. If no needless legislation will be necessary which may through extensive testing economically bar a small cosmetic manufacturer or prevent a new cosmetic manufacturer from going into business.

Mr. KLEINFELD. Perhaps you did not understand my question. You said you perform these careful tests; is that correct?

Mr. SOROKO. That is correct.

Mr. KLEINFELD. And you said you perform them because you want the public to be protected.

Mr. SOROKO. That is right, and want to protect our interests.

Mr. KLEINFELD. Should not everybody do the same thing?

Mr. SOROKO. They should.

Mr. KLEINFELD. If they don't there may be injuries caused, is that right?

Mr. SOROKO. That answers itself. That is right.

Mr. KLEINFELD. In fact, if some companies perform these tests—which are rather expensive, are they not?

Mr. SOROKO. Well, they are expensive, except that they could be conducted through a body or a group such as we have suggested, which would not be expensive.

Now, there may be some objection to the committee on cosmetics of the American Medical Association or some other group like that, but for that matter that objection should not be a serious one, because in the Food and Drug law now it is mandatory for a manufacturer to produce products that are only approved by the pharmacopoeia, which is a similar group.

Mr. KLEINFELD. Then you think that some such device as you mention might well enable the smaller cosmetic manufacturer or distributor to make these tests?

Mr. SOROKO. Without injuring them. That is correct.

Mr. KLEINFELD. And without injuring the public?

Mr. SOROKO. That is correct.

Mr. KLEINFELD. That is all.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. No questions.

The CHAIRMAN. Mr. Horan?

Mr. HORAN. Have you ever had any cases of people working in your production plants and being subjected to these materials in great

quantities, both in the air and by actual contact—have you had any reaction there to your knowledge?

Mr. SOROKO. We had one particular case of a girl who was highly sensitive to perfume, and we found when she went into the perfume department she had a dermatitis on the neck and hands. We moved her into the lipstick department and she was well again within a few days.

Mr. HORAN. She was all right then?

Mr. SOROKO. Yes.

Mr. HORAN. My reason for asking that question is because it is one that should be asked and should be asked in all fields.

I come from an area where we use a lot of pesticides and we are just as concerned as I know the cosmetic industry is that the public know we are trying to meet these problems. We find people working in these plants where they mix pesticides, and quite often we have cases.

Undoubtedly some publicity as to what happens to the people who work with these cosmetics during the course of the manufacture ought to be made as a part of the hearings. That is the reason I asked you this question, Mr. Soroko.

You just had one?

Mr. SOROKO. That is all in 20 years we know of. That does not mean if we would have had more employees the percentage or the answer would be different. We have approximately 1,500. Now if we had had 15,000 we might have had four, but the difference between a reaction of the skin as a result of the primary irritant and that of an allergen is just that the reaction of an allergen disappears with the removal of the offending agent, or sometimes that is a chemical reaction of the individual person who at that particular time has a personal idiosyncrasy toward that something at that particular time.

The CHAIRMAN. Could you tell me how the AMA is supported financially?

Mr. SOROKO. I would have to give you this as the legal profession calls hearsay—from what I have heard.

The CHAIRMAN. I mean if they are able to take a product and analyze it and give a report on it and there is no charge made for that——

Mr. SOROKO. That is correct.

The CHAIRMAN (continuing). I am interested in how they sustain themselves financially.

Mr. SOROKO. The AMA until several years ago never charged their membership any dues, I understand, and their moneys were derived from various endowments that were given to them by doctors who died and left money in their wills. But most of their current moneys I believe is from their convention. They have an annual convention and they have exhibitors whose products are marketed to the doctors like pharmaceutical houses and equipment houses.

The CHAIRMAN. It comes from the trade, the principal source of support?

Mr. SOROKO. From the pharmaceuticals. I think it is a nonprofit organization as far as any individual is concerned.

The CHAIRMAN. Thank you.

Mr. KLEINFELD. Is a representative of the Dorosy Sales Corp. here?

Mrs. HERRMANN. Yes.

The CHAIRMAN. Your name and address?

Mrs. HERRMANN. Dorothy Herrmann, 489 Fifth Avenue, New York City.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF MRS. DOROTHY HERRMANN, REPRESENTING DOROSY SALES CORP., NEW YORK CITY

Mr. KLEINFELD. What is your connection with the Dorosy Sales Corp.?

Mrs. HERRMANN. I formerly was the owner of the Dorosy, Inc., now operating as Dorosy Sales Corp. I was the manufacturer and distributor of one product known commercially as Kix Kinks. This product is used for straightening hair. It is sold only for professional use in beauty salons and not at retail for general public consumption.

Do you wish me to read further?

Mr. KLEINFELD. You might as well.

Mrs. HERRMANN. The ingredients contained in the product are as follows:

(The list of ingredients is in the files of the committee.)

Mrs. HERRMANN. The labels for the product have a notation in bold type directing the user to follow an instruction sheet which accompanies each jar of Kix Kinks. These instruction sheets itemize detailed steps to follow in applying the preparation.

We have found that this preparation, when applied to the skin, is an irritant. Tests were conducted to find an adequate covering to protect the scalp while the preparation is being applied to the hair. These tests showed that an efficient covering is petroleum jelly, commonly known as vaseline. The instruction sheet specifies the use of vaseline as a protective covering, and specifies the use of rubber gloves by the operator. When the product is applied with these simple precautions, we have found it to be harmless.

Our tests have also shown that the preparation is detrimental to bleached or dyed hair, and for that reason the instruction sheet prohibits use on hair which has had such treatment. Our tests have shown further that the product might cause breakage if applied to the hair of people of the Negro race. Kix Kinks has never been marketed in that segment of the cosmetic market, and the instruction sheet specifically prohibits its use on the hair of Negroes.

The instructions emphasize the fact that the preparation is not be in contact with the scalp or skin at any time. As a further precaution, the instructions specify that a test be made on a curl of the hair which is to be treated to observe the reaction before treatment is undertaken.

The formula for this product is on file with the Pure Food and Drug Administration and periodic checks have been made by that agency during the last few years. Our preparation is fully covered by products liability insurance and our experience has shown that the number of claims is negligible.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. You say in your statement that you make only one product known as Kix Kinks?

Mrs. HERRMANN. Right.

Mr. KLEINFELD. You don't make a reconditioning cream?

Mrs. HERRMANN. No.

Mr. KLEINFELD. Did you ever?

Mrs. HERRMANN. A reconditioning cream?

Mr. KLEINFELD. Yes.

Mrs. HERRMANN. Yes, some years ago we made a reconditioning cream.

Mr. KLEINFELD. Now you only make this one product.

Mrs. HERRMANN. That is right. It was not marketed under this corporation, though.

Mr. KLEINFELD. I see. You say that tests were conducted to find an adequate covering to protect the scalp when your preparation was being applied to the hair. You say also that your tests have shown that the preparation is detrimental to bleached or dyed hair and to the hair of Negroes.

How long has this product been on the market?

Mrs. HERRMANN. Fifteen years.

Mr. KLEINFELD. Who conducted these tests for you?

Mrs. HERRMANN. We conducted them through schools, through beauty salons, through models, through individuals.

Mr. KLEINFELD. Did you have the tests performed by dermatologists?

Mrs. HERRMANN. We also had a dermatologist.

Mr. KLEINFELD. What was his name?

Mrs. HERRMANN. A very famous dermatologist in Chicago, who is a Negro.

Mr. KLEINFELD. What is his name?

Mrs. HERRMANN. I can't remember. He is a very famous man.

Mr. KLEINFELD. Would you mind furnishing it to the committee?

Mrs. HERRMANN. I can find out, yes.

Mr. KLEINFELD. Your firm has been in legal difficulties with the Food and Drug Administration in the past, has it not?

Mrs. HERRMANN. Not to my knowledge, no.

Mr. KLEINFELD. Were you with the company in 1942?

Mrs. HERRMANN. Yes, I was.

Mr. KLEINFELD. Isn't it a fact that a shipment of your product was seized by the Government on the ground that it contained a poisonous substance, namely, sodium hydroxide?

Mrs. HERRMANN. I see. Of course, it contains that. But they seized the shipment because that particular shipment was supposed to have had more than the 5 percent. It was corrected, and I think after that it approved all the tests and has ever since.

Mr. KLEINFELD. And wasn't a criminal action also brought against your company based on shipments to Illinois, Ohio, and other States on the ground that your article was adulterated in that it contained a poisonous or deleterious substance, sodium hydroxide, which rendered the product injurious to users?

Mrs. HERRMANN. I think that is the same of which I speak.

Mr. KLEINFELD. And a plea of guilty was entered in that case?

Mrs. HERRMANN. Yes.

Mr. KLEINFELD. You say that your instructions point out that there must be a covering of petroleum jelly or vaseline?

Mrs. HERRMANN. That is right.

Mr. KLEINFELD. And those instructions are given to the operators of the beauty salon; is that right?

Mrs. HERRMANN. Correct.

Mr. KLEINFELD. If that precaution is not taken, and if it is not a sufficient covering of petroleum jelly, there may well be some serious injury; isn't that correct?

Mrs. HERRMANN. There might.

Mr. KLEINFELD. So that it is very important that the beauty-shop operator observe the very specific precautions which you indicate should be followed?

Mrs. HERRMANN. I would say so.

Mr. KLEINFELD. Do you change your formula from time to time?

Mrs. HERRMANN. The formula for our product?

Mr. KLEINFELD. Yes.

Mrs. HERRMANN. The formula has been perfected. The formula was perfected after 1942.

Mr. KLEINFELD. It was perfected after these two legal actions of which we spoke?

Mrs. HERRMANN. That is right.

Mr. KLEINFELD. And since that time you have not changed your formula?

Mrs. HERRMANN. We have had no difficulty.

Mr. KLEINFELD. How many complaints per year would you say you receive?

Mrs. HERRMANN. Very few. They are negligible.

Mr. KLEINFELD. About how many?

Mrs. HERRMANN. I have no way of knowing. They are given into the hands of our attorney, but they are very small.

Mr. KLEINFELD. What types of complaints are they?

Mrs. HERRMANN. Where the operators refuse to read directions. Carelessness of applications, primarily.

Mr. KLEINFELD. And what happens to the person upon whose hair the product is to be applied when these beauty operators do not follow directions?

Mrs. HERRMANN. Some have a slight irritation, which usually disappears. Others make use of the complaint, as they do in other cosmetics, where they try to be reimbursed for their inconvenience.

Mr. KLEINFELD. Do your directions also state that the product should not be applied to the head where there is any broken or irritated skin?

Mrs. HERRMANN. In more than one section of the sheet, as well as the label of the product.

Mr. KLEINFELD. And have these injuries been due to the fact that the product has been applied in situations where there has been some broken or irritated skin?

Mrs. HERRMANN. Where there has been broken?

Mr. KLEINFELD. Broken or irritated skin.

Mrs. HERRMANN. Yes.

Mr. KLEINFELD. And the complaints have recited to you that they had some irritation on the scalp? Is that the ordinary complaint?

Mrs. HERRMANN. In some cases, yes.

Mr. KLEINFELD. And what other complaints have you received?

Mrs. HERRMANN. Well, where the operator applied it to a dyed head they had some breakage.

Mr. KLEINFELD. Some loss of hair?

Mrs. HERRMANN. Yes. But the hair grows back again. It is only a temporary discomfort.

Mr. KLEINFELD. That is all.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. Where is your plant located?

Mrs. HERRMANN. 220 West Forty-second Street.

Dr. HEDRICK. Here in New York City?

Mrs. HERRMANN. That is right.

Dr. HEDRICK. How many employees do you have?

Mrs. HERRMANN. We employ a chemist who makes and manufactures the product; that is manufactured by him.

Dr. HEDRICK. What school did this chemist graduate from?

Mrs. HERRMANN. I don't know, but I think Johns Hopkins.

Dr. HEDRICK. Do you know the degrees he has?

Mrs. HERRMANN. Yes, he has various—I can find them for you and give them to you.

Dr. HEDRICK. How long have you been making this product?

Mrs. HERRMANN. How long?

Dr. HEDRICK. Yes.

Mrs. HERRMANN. This particular chemist has made the product, let's see, about 10 years.

Dr. HEDRICK. Do you carry insurance to protect you?

Mrs. HERRMANN. Yes, we have full coverage product liability.

Dr. HEDRICK. How many times has your company had to pay money in order to clear up suits against your company?

Mrs. HERRMANN. Not very many.

Dr. HEDRICK. About how many?

Mrs. HERRMANN. I don't know. They have a record.

Dr. HEDRICK. Has it been more than one time?

Mrs. HERRMANN. I don't know.

Dr. HEDRICK. Your insurance company would know?

Mrs. HERRMANN. Yes, it would.

Dr. HEDRICK. What effect does this have on the hair? Does it create a blister formation on the scalp if not used properly?

Mrs. HERRMANN. Yes, a slight tingling. I have kinky hair myself, so I think I can adequately answer that. My hair has been straightened.

Dr. HEDRICK. Is your hair kinky now as a result of the use of this preparation?

Mrs. HERRMANN. Is it kinky as a result of the use of it?

Dr. HEDRICK. Yes.

Mrs. HERRMANN. I hope not. I hope it is straight as a result of the use of it.

Dr. HEDRICK. How many employees do you say you have in the plant besides the chemist?

Mr. HERRMANN. Well, the sales force.

Dr. HEDRICK. How many does that consist of?

Mrs. HERRMANN. Pardon?

Dr. HEDRICK. How many in your sales force?

Mrs. HERRMANN. I don't know. It is a new corporation called Dorosy Sales. I don't know how many they employ.

Dr. HEDRICK. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. Is Dorosy, Inc., one company?
Mrs. HERRMANN. That was; yes.
Mr. HORAN. Is it now dissolved?
Mrs. HERRMANN. That is right.
Mr. HORAN. And you both manufacture and distribute under the firm name of Dorosy Sales Corp.; is that correct?
Mrs. HERRMANN. They do.
Mr. HORAN. They are not two separate institutions?
Mrs. HERRMANN. One is a dissolved one, the other one is an active one.
Mr. HORAN. That is all, Mr. Chairman.
The CHAIRMAN. That is all. Thank you.
We will recess until 2 o'clock.
(Whereupon, at 12:30 p. m., the committee adjourned, to reconvene at 2 p. m., this same day.)

AFTERNOON SESSION

(The committe reconvened at 2 p. m.)
The CHAIRMAN. The committee will come to order.
Mr. KLEINFELD. Is Dr. Mayer here?
Dr. MAYER. Yes, sir.
The CHAIRMAN. Your name and address, please?
Dr. MAYER. R. L. Mayer, 52 Mountain Avenue, Summit, N. J.
(The oath was administered by the chairman.)
The CHAIRMAN. You may proceed.

TESTIMONY OF R. L. MAYER, M. D., SUMMIT, N. J.

Mr. KLEINFELD. Dr. Mayer, from what university did you obtain your degree of doctor of medicine?
Dr. MAYER. Freiburg.
Mr. KLEINFELD. Germany?
Dr. MAYER. Yes.
Mr. KLEINFELD. What year?
Dr. MAYER. In 1920.
Mr. KLEINFELD. Did you then practice medicine?
Dr. MAYER. No; I never did practice medicine. I was a research worker.
Mr. KLEINFELD. And you studied chemistry?
Dr. MAYER. I did.
Mr. KLEINFELD. Where?
Dr. MAYER. Freiburg and Berlin.
Mr. KLEINFELD. And then what did you do?
Dr. MAYER. I was head of the laboratories in a university clinic in Breslau for 8 years.
Mr. KLEINFELD. What university?
Dr. MAYER. The University of Breslau.
Mr. KLEINFELD. Proceed.
Dr. MAYER. Then I went back to France—I was born in France—and was head of the microbiology department of the Rhone-Poulenc, a chemical concern in Paris for 10 years.
Mr. KLEINFELD. What is your present position, sir?
Dr. MAYER. I am chief microbiologist in the research department of CIBA Pharmaceutical Products Inc., in Summit, N. J.

Mr. KLEINFELD. How long have you been chief microbiologist of that company?

Dr. MAYER. Since February 1943.

Mr. KLEINFELD. And what generally do your duties consist of?

Dr. MAYER. I am head of a division in which new pharmaceutical products are being studied.

Mr. KLEINFELD. What types of products does CIBA manufacture?

Dr. MAYER. Two kinds: One, hormones, of very considerable significance; I was responsible for pyribenzamine which we are manufacturing, and we manufacture a great variety of other pharmaceutical products.

Mr. KLEINFELD. These products are drugs?

Dr. MAYER. They are used by sick people.

Mr. KLEINFELD. Will you please read your statement, Doctor?

Dr. MAYER. The two possible health problems created by the absorption of the dyes which are currently being used for coloring foods, cosmetics, and drugs deal with allergic sensitization and cancer. In discussing these two points it is necessary to consider these problems as aspects of a still broader field since incriminated food dyes are not the only substances to produce such effects; they belong to a great and important group of substances, all having similar chemical and physiological properties.

Allergic sensitization: A great number of synthetic chemical compounds are capable of producing allergic sensitizations. Of particularly strong sensitizing power are the aromatic amines, a group of products derived from coal tar. Many substances of this group have been know for a long time as causing many occupational and nonoccupational allergies. Many food dyes, cosmetic dyes, and dyes used in the pharmaceutical industry, belong to this group.

The aromatic amines occupy a very predominant place as a cause of allergy and other pathological conditions because they are used in large quantities and are chemically very reactive. It is well known that many substances of high chemical activity are also very powerful poisons and strong sensitizers.

The most reactive members of this group and consequently the most powerful poisons and allergens are aniline, paraaminophenol, paraphenylenediamine, certain nitro compounds, certain aromatic medicants containing amino groups, and certain azo dyes, the latter group containing many food and similar dyes.

Allergenic substances of similar chemical configuration form well-characterized allergenic groups. Since their chemical reactions are identical and one substance can replace another as an allergenic poison, they are, so to speak, interchangeable as allergens. An allergy for instance established by and against one aromatic amine often extends from the very outset to many others, sometimes to the whole group of chemical relatives. We speak here of group allergy and group hypersensitiveness. A woman, for instance, who had dyed her hair with a hair dye containing paraphenylenediamine, and was sensitized by this dye, would react strongly with a dermatitis to further applications of this dye as well as to her furs dyed with the same substance. Upon skin tests with paraphenylenediamine she proves extremely sensitive, but as shown by patch test with related chemicals, she also has become sensitive to many other aromatic amines as well as to objects treated

with them, such as aniline, aminophenol, azo dyes, including certain food dyes.

The question, of course, arises as to why such food dyes have been released and their use permitted. All dyes destined for use as food colors have been submitted to classical toxicity tests intended to prove that they are nonpoisonous, and secondly to a sensitization test to show that they do not produce sensitization.

All dyes regularly used as food dyes, including those belonging to the group of aromatic amines, have passed this test because they prove to be nontoxic in high concentrations, and failed to produce sensitizations.

I have been able to show in experimental sensitizations that certain of the food dyes which are unable to produce sensitizations in nonallergic individuals are nevertheless able to elicit strong reactions in sensitized individuals.

A person, such as a woman we just cited as an example has become strongly sensitized to a paraphenylenediamine after the use of this substance as a hair dye. In many instances such persons have become, as a consequence, automatically sensitive to certain food dyes belonging to the same chemical group as the hair dye. These food dyes are able to excite the previously acquired sensitization to paraphenylenediamine. Such food dyes are therefore allergic elicitors, although they are not allergic sensitizers; they are incapable of producing a new allergy in a nonallergic individual but they are able to bring about a flare-up of an existing allergy.

In principle, these results obtained in experimental animals have been verified in humans and I personally believe that certain individuals who are specifically and strongly sensitized to certain aromatic amines do not tolerate certain azo dyes as food colors or in cosmetics.

Carcinogenesis: A much more serious attack against the use of azo dyes in foods has come from cancerologists. Intestinal cancer has increased throughout the world and the question has been discussed by authoritative scientists, especially in Europe, as to whether the very heavy constant absorption of certain food dyes is not responsible for this increase in intestinal cancer. These discussions were prompted by the experimentally proven fact that certain of the food dyes, just discussed as allergens, are capable of producing occupational cancer in humans and experimental cancer in animals.

It has been known for over 50 years that chemical workers, who are in steady contact with certain aromatic amines or azo dyes, suffer a much higher percentage of cancer of the bladder than any other group. Animal experiments have proven that certain aromatic amines and azo dyes, especially butter yellow, are capable of producing precancer and cancer in various animals.

In spite of these clinical and experimental observations, we do not have any direct and strict proof that azo dyes used in foods are responsible for the increased cancer incidence in man. However, the problem urgently requires our attention.

Conclusion: There are strong indications that some azo dyes now commonly used as food dyes, and for the coloring of cosmetics and drugs, may elicit and entertain certain allergic manifestations. It has also been claimed that certain food dyes are responsible for the increased incidence of intestinal cancer.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Doctor, these dyes which you speak of, do you know whether any of them are presently in use in foods or cosmetics?

Dr. MAYER. Yes, they are dyes which are able to produce elicitation of a present allergy and which are permitted to be used for dyeing foods and cosmetics. Some of those dyes are, for instance, food, drug, and cosmetic dye yellow No. 3, or yellow No. 6, or orange No. 2.

Mr. KLEINFELD. Do you know, Dr. Mayer, whether certain of these azo dyes have recently been prohibited for food use in Germany?

Dr. MAYER. I happen to have here a paper on a study of certain dyes, a paper published in 1949 in Glasgow, in which a Mr. A. H. Emcarden has shown that one of the substances permitted as food dyes produced cancer, and this dye was promptly prohibited for use as a food dye.

Mr. KLEINFELD. Where was this?

Dr. MAYER. In England, at the Royal Cancer Hospital in Glasgow, Scotland. This is one of those incidents to which you were referring.

Mr. KLEINFELD. Was this published, Doctor?

Dr. MAYER. Yes, this was published in the Glasgow Medical Journal in October of 1949. And there is also another very extensive paper on the same subject.

I personally believe that the question of allergy and sensitization and skin eruption is a very secondary affair and the number of possible dermatitis and diseases produced by these allergies is very small and unimportant as compared to many other possibilities.

However, the problem of cancer is a very serious one. It has been discussed recently and very extensively by Professor Bauer in Switzerland and by a Dr. Reding, in Brussels who published a paper in the Acta de l' Union Internationale-Contre le Cancer.

Mr. KLEINFELD. Then the problem which concerns you is the possible carcinogenic effect of some of these dyes?

Dr. MAYER. I was interested personally in this problem in the very beginning only from a dermatological point of view, and then I approached this problem from a biochemical, more theoretical angle trying to find the chemical reason for the ability of these substances to produce skin diseases and cancer.

I published a great number of papers on this problem. I feel that although there are no proofs that food dyes may be responsible for cancer, the suggestive possibility is very great.

Mr. KLEINFELD. Very great?

Dr. MAYER. Yes.

Mr. KLEINFELD. Then what do you recommend, Doctor—that much greater and more intensive research be done?

Dr. MAYER. I think so; yes. I do not think that it is possible today to prohibit all these food dyes. There is not enough definite evidence for such a step.

It is known that dyes which are more dangerous than others are prohibited and others are being withdrawn as soon as it has been proven that they are dangerous. But to prohibit the use of all dyes without knowing that they do produce cancer would be a very drastic move. And, naturally, I don't think that this would be feasible.

Mr. KLEINFELD. Are there substitutions?

Dr. MAYER. Many vegetable dyes, and they are probably much less dangerous. On the other hand, it would be quite interesting to revise

one day the whole list of products actually used as food dyes. There are now so many new dyes being synthesized which may be different from the azo dyes, that it would be interesting to test these.

Mr. KLEINFELD. As I gather your point, Doctor, you feel that we don't know definitely now that some of these dyes which are currently in use are carcinogenic, but that you have your suspicions of them?

Dr. MAYER. It is known from many dyes. I do not know exactly from how many. It is very hard to find out how many dyes and which dyes are used as food dyes in the world. But in Dr. Reding's paper there is a very excellent list of all these substances and their possible carcinogenic activities, their use as dyes; of course, they are used mostly in Europe.

Mr. KLEINFELD. What is the name of that paper and where did it appear, Doctor?

Dr. MAYER. It appeared in Brussels in the Acta Union International against cancer.

Mr. KLEINFELD. That is all.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. No questions.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. I am very interested, Doctor, in what you have said. One of our witnesses yesterday from a very reputable firm, I might add, gave us as one of his recommendations for our consideration that consideration should be given to more freedom and liberation in the use of colorings in cosmetics. I suppose he meant lipstick and nail covering or wherever coloring is used in cosmetics. Now what is your reaction to that?

Dr. MAYER. I am personally convinced that many food dyes are absolutely harmless, and it is in the interest of all manufacturers to use only products which are completely innocuous. Otherwise they would lose money.

Mr. HORAN. The witness that asked for this consideration was a very responsible individual.

Dr. MAYER. I think it is in their own interest not to use any substances which may be dangerous. On the other hand, it never will be possible to prevent all dangers or irritations. There do not exist any products in the world which would be 100 percent safe.

Mr. HORAN. As the chairman has indicated then, we are getting right back, as we always do, to the establishment of a research group or a group that can arrive at a certain socially safe judgment that we can depend on.

Dr. MAYER. That is right.

Mr. HORAN. Isn't that what we get back to all the time?

Dr. MAYER. I think so.

Mr. HORAN. Yes. He was from Coty's, which is a very reputable firm, and we were impressed with his testimony. I bring this out because this is part of the record. He says, "We believe, however, that the regulations governing the certification of colors are too strict."

And of course that implies dyes or some other ingredient that will give colors to cosmetics.

Dr. MAYER. I do not agree with this view. Among 900,000 responsible persons there may be only one who is not responsible and may introduce a dangerous color, and this one person out of 900,000 may be responsible for a rather terrible danger for the entire population.

Mr. HORAN. Of course that is true. If it wasn't for 10 percent of our population we would not have to have any government possibly.

Dr. MAYER. That is right.

Mr. HORAN. But we get back to the fact of what sort of an institution should we set up to pass on these things that trouble you and trouble all of us.

Dr. MAYER. I don't believe that the man who gave you this testimony is absolutely correct. We should not release any chemical product or give any liberty to a cosmetic firm to use whatever dye it may want to use, because this could be very dangerous.

I think it is necessary to set up a testing and selecting committee which bases its views and its proposition on experimental data a committee of research workers who have sufficient experience in this field.

Mr. HORAN. This man apparently knew what he was doing. He was close to the manufacturing of these products, and the reputation of this particular firm is good enough so I know he feels his responsibility. And apparently there are regulations which he says are too strict in his opinion.

Dr. MAYER. I do not know of them, so I could not say.

Mr. HORAN. I don't either.

Apparently, regarding colorings in cosmetics, regulations exist which some of the reputable and time-tested companies that have been putting out cosmetics for years think are too strict. Now you come along with testimony here which is very interesting and obviously sincere, but you raise the question of dyes, which, of course, brings up the whole subject of coloring.

I want it made very clear that these regulations are not something passed by Congress, they are implementations of the intent of Congress after we have passed the statute and turned it over to the administrators, who have then put the intent of Congress into effect in an active way, and that is where the regulations come from.

Now, regarding dyestuffs, the regulations, according to one reputable witness, are too strict already; that is, dyestuffs used in cosmetics.

Dr. MAYER. I don't think the regulations are too strict, because the dye regulations are very similar to those governing the application and the sale of drugs. The Food and Drug Administration has set up very strict regulations for the introduction of all new drugs. Nobody is permitted to introduce and sell a new drug without having it tested very thoroughly for possible dangers and for tolerance.

I know from my own experience in our firm that it is sometimes very difficult to comply with all those regulations and problems, but I feel that they are necessary, because there are always some people who just would not use good sense.

Mr. HORAN. I appreciate your response. I want to ask one more question.

What agency do you think the people of America would accept as an agency to conduct those experiments, and having once conducted them fully and completed the research, to find out whether or not these allegations were so or not, what agency do you think the public would accept?

Dr. MAYER. I think the Food and Drug Administration which already exists.

Mr. HORAN. May I ask you one question based on that? Are they not the enforcing agency?

Dr. MAYER. Yes; they are.

Mr. HORAN. Should a policeman write your statutes by which you govern the city, or should it not be some other body, a council perhaps?

Dr. MAYER. I do not think that they are only enforcing agents.

Mr. HORAN. Well, they are.

Dr. MAYER. They are enforcing but their enforcement is based upon research and advice from many sources.

Mr. HORAN. Well, I will ask it another way.

This is the crux of the whole thing so far as I am concerned. Do you think that one body in our society should be the policeman, the prosecutor, and judge all in one?

Dr. MAYER. I do not think so.

Mr. HORAN. Then you would have to correct your answer to me, because the enforcing agency is the Food and Drug Administration. And they have done a beautiful job and I am for them. But the tolerances and the standards that they enforce I think ought to come from another body. It is part of the nature of our Government of checks and balances.

Dr. MAYER. I think it would be very useful to set up an independent committee or research body to study this problem. On the other hand I know that this problem of the carcinogenic properties of food dyes is studied all over the country. It is not necessary to establish a new committee, but it would be useful to unite and bring all these different researchers together.

Mr. HORAN. We had a Dr. Grolnick this morning that suggested the bringing together of the Food and Drug Administration, the American Medical Society's committee on cosmetics, and the Public Health Service.

Dr. MAYER. Yes.

Mr. HORAN. I believe he also suggested one other body. He wanted them to get together and find out if we couldn't, out of what exists already, construct something that could evaluate the problem and arrive at standards, which in turn could be enforced by the Food and Drug Administration. I think it would be a service to the Food and Drug Administration, because we put them under a tremendous strain today when we asked them to enforce regulations where they do not have established standards by which to enforce them. That is our danger.

Dr. MAYER. The great difficulty is the fact that commercial interests are involved, and very heavily involved, which will always bring pressure upon acceptance rather than on refusal.

Mr. HORAN. Then isn't that all the more reason for having an unbiased body to arrive at standards?

Dr. MAYER. Yes.

Mr. HORAN. Thank you.

The CHAIRMAN. Mr. Kleinfeld has another question.

Mr. KLEINFELD. Dr. Mayer, in your experience in your field of activity, have you come into contact with the administration of the new drug section of the law?

Dr. MAYER. Yes.

Mr. KLEINFELD. In your opinion has it worked out all right?

Dr. MAYER. The new drug section as far as it is applied by the Food and Drug Administration?

Mr. KLEINFELD. That is right.

Dr. MAYER. Our firm regularly makes application to the Food and Drug Administration for the passing of new products or new indications of products, and I do not think that we have had any difficulties so far. All objections and recommendations I saw made from the Food and Drug Administration were justified.

Mr. KLEINFELD. Doctor, I have here a book entitled "Historic Meeting To Commemorate Fortieth Anniversary of Original Federal Food and Drug Act," put out by the Commerce Clearing House in 1946. One article is entitled "Its Basic Value to Cosmetic Industry," by H. Gregory Thomas, vice president of Bourjois. And in part here is what he says:

> International law has failed through lack of sanctions. Domestic laws can also fail when sanctions are applied ruthlessly or loosely; both will ultimately destroy the law itself. It should always be a pride to our Government, and to the Food and Drug Administration, that its field officers, its inspectors, have mirrored the high purpose and integrity of their Washington superiors, and have so often led manufacturers through the technicalities of the law and its regulations to full compliance, in the interest of the consumer and the improvement of the product.
>
> We inaugurated an era of mutual confidence and mutual help. I stand here today to say, on behalf of the cosmetic industry, that we are not only satisfied but grateful for the way in which our problems have been met and solved.

That appears to indicate that, as far as this gentleman is concerned, representing and speaking for the cosmetic industry, that industry was satisfied with the way the Food and Drug Administration was administering the law; is that correct?

Dr. MAYER. I think so; and I think the same applies to the drug industry.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Thank you, Doctor.

Mr. KLEINFELD. Dr. Giles.

The CHAIRMAN. Your name and address, Doctor.

Mr. GILES. I. V. Giles, Primrose House, 420 Lexington Avenue, New York, N. Y.

(The oath was administered by the chairman.)

TESTIMONY OF I. V. GILES, CHIEF CHEMIST, REPRESENTING PRIMROSE HOUSE, INC., NEW YORK CITY, AND THE BARBASOL CO., INDIANAPOLIS, IND.

Mr. KLEINFELD. Dr. Giles, you are chief chemist for the Barbasol Co.?

Mr. GILES. Yes, sir.

Mr. KLEINFELD. And what is the relationship between the Barbasol Co. and Primrose House, Inc.?

Mr. GILES. Barbasol Co. controls Primrose House and manufactures most of its products, manufactures and sells most of its products.

Mr. KLEINFELD. Pardon me. Would you mind speaking louder? I do not think the committee can hear you. Would you mind repeating that?

Mr. GILES. Barbasol Co. controls Primrose House, Inc., and manufactures and sells most of the items that are handled in the Primrose

House line. We sell all of them. My statement will show the ones we do not manufacture.

Mr. KLEINFELD. Will you please read your statement?

Mr. GILES. I have a little bit of bronchitis, and I hope you will forgive my voice.

Part I: We manufacture and/or distribute some 38 items in our Primrose House line. These can be classified as creams, lotions, perfumes and toilet waters, face powders, and make-up items.

(A list of the items is in the committee's files.)

There are five additional items which we do not manufacture. They are lipsticks, chiffon touch-up, dry rouge, cream rouge, and mascara. All of these are purchased from Kolmar Laboratories, either from their Milwaukee, Wis., or Port Jervis, N. Y. plants. This is a reputable house which is a leading manufacturer of these types of products for the entire cosmetic industry.

(The names of ingredients used are on file with the committee.)

We do not feel that it is desired by this committee that we reveal publicly what some of our emulsifiers and other raw materials are. This in our opinion is a trade secret. We can assure the committee that these products are commonly used in the industry, their safety is assured by reputable manufacturers, and that use tests to prove their safety have been made before introducing the products in interstate commerce.

Part II: This section relates to the raw materials used, control in manufacture, use tests of products containing new ingredients, and so forth.

All Primrose House products, except a few as indicated in part I, are manufactured for Primrose House by the Barbasol Co., which controls and operates Primrose House, Inc.

When the ingredients in our formulation are listed in the United States Pharmacopaeia and National Formulary, or are included in the specifications of the Toilet Goods Association we purchase by and apply these standards. If the ingredients are not included in one of the above we purchase on specifications from reputable manufacturers. All of our ingredients are, to my knowledge, safe to use in cosmetics and are used by the industry.

As a routine matter all raw materials are tested, by a graduate chemist, to determine whether they conform with United States Pharmacopaeia, National Formulary, TGA, or the manufacturer's standards.

The processing of ingredients to finished products is under the supervision of a chemist or chemical engineer, according to directions and formulas supplied by the laboratory office. The finished products are tested for physical and stability properties before being shipped.

All new products or products containing new ingredients are given use tests. A group of employees and others are used for these tests. In cases where we think it advisable, we use the patch-test method of evaluating the suitability of an ingredient or product. The patch test we use is essentially that described by Drs. C. Guy Lane and Irvin H. Blank of the Department of Dermatology of Harvard Medical School, and the Massachusetts General Hospital, and published in the American Perfumer, April 1948, page 357.

Primrose House has carried product liability insurance for many years. At present the insurance is carried by the United States

Casualty Co., New York City. We have never had any complaints from the insurance company which considers our safeguards adequate.

Our manufacturing and laboratory facilities have been inspected by several agencies of the United States Government, including the Medical Procurement Agency, Chemical Procurement, and Veterans' Administration within the past 18 months, and we have been approved for competitive bidding on items these agencies require. We have been awarded contracts on some of these items.

Part III. Recommendations: We do not feel that there is need for additional legislation regulating the cosmetic industry. The present laws, in our opinion, are adequate.

If any additional legislation is enacted it might require that the manufacturers have adequate laboratory facilities and competent chemists and technical men to supervise the formulation, processing, and testing of the raw materials and finished products. This is now the practice in the major portion of the industry.

By major portion there I mean percentagewise. I mean by volume sold. As I understand it, there are a few smaller concerns who just do not have the facilities.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Doctor, are your products submitted to the Committee on Cosmetics of the American Medical Association for acceptance?

Mr. GILES. No, sir.

Mr. KLEINFELD. Any of them?

Mr. GILES. No.

Mr. KLEINFELD. On page 5 of your statement you say all your new products or products containing new ingredients are given use tests. Who gives those tests?

Mr. GILES. They are under my supervision and the sales department. We have a panel consisting of employees in the organization and selected people in that city and in other places who get samples of every product we are going to put on the market, or even a change in product.

We came into possession of Primrose House in 1944. That has been operating for some 10 or 15 years prior to that. And there was no such thing done, and we were working our heads off trying to make that and all the Barbasol the Army could use and everything else. We didn't get around to this testing of things like this until raw materials cleared up after the war so we could get raw materials. In the meantime a lot of new ingredients had come into use, and we revised some of the formulas. In cases where we revised the formulas—panel tests were made within our organization. I will say that much.

Mr. KLEINFELD. Are these use tests given under the supervision of a dermatologist?

Mr. GILES. No, sir.

Mr. KLEINFELD. On how many people are these use tests applied?

Mr. GILES. Anywhere from 25 to 100 depending on what—I think I said in there we give patch tests sometimes on the ingredients.

Mr. KLEINFELD. Let's take the use test.

Mr. GILES. All right.

Mr. KLEINFELD. How many people get use tests?

Mr. GILES. Anywhere from, not less than 25, anywhere to 100.

Mr. KLEINFELD. And you judge the results?

Mr. GILES. Yes.

Mr. KLEINFELD. You are a chemist?

Mr. GILES. I fix up questionnaires?

Mr. KLEINFELD. Doctor, it is getting a little late. If you have to make an explanation, all right, but if you can answer yes or no, why don't you try to do so? You are a chemist?

Mr. GILES. Yes.

Mr. KLEINFELD. You don't employ dermatologists to give these use tests; is that correct?

Mr. GILES. That is right.

Mr. KLEINFELD. How about patch tests—who gives the patch tests?

Mr. GILES. I do.

Mr. KLEINFELD. No dermatologist?

Mr. GILES. No.

Mr. KLEINFELD. How many patch tests do you give?

Mr. GILES. A minimum of 25.

Mr. KLEINFELD. Maximum of how many?

Mr. GILES. I would say 50. We have made as many as 50.

Mr. KLEINFELD. Do you know about the recommendations on patch tests that have been made by people like Dr. Louis Schwartz and Dr. Peck and other dermatologists?

Mr. GILES. I have heard Dr. Schwartz and others speak before the Toilet Goods Association.

Mr. KLEINFELD. Do you know how many patch tests he recommended?

Mr. GILES. I believe they recommended a hundred or more.

Mr. KLEINFELD. You don't do that, do you?

Mr. GILES. No, sir.

Mr. KLEINFELD. You say that in cases where you think it advisable you use patch tests, so that you don't use them in all cases for your products; is that correct?

Mr. GILES. Frankly, we have turned out very few new products. We have modified some of the products. We have eliminated some, and we have added a few.

Mr. KLEINFELD. In those cases where you modify your formulas or make new products you don't always make patch tests; is that correct?

Mr. GILES. That is right.

Mr. KLEINFELD. You say, Doctor, that you do not feel that it is desired by this committee that you reveal publicly what some of your emulsifiers and other of your raw materials are, that in your opinion it is a trade secret.

There is no way, of course, that this committee can ascertain whether your raw materials or products are or are not safe unless we have those names. The other people here gave us this information. Is there any reason why you will not?

Mr. GILES. I started to put those in, and our management said—of course, I am not an officer of the company—that that was a trade secret. Now I can supply that.

Mr. KLEINFELD. Will you do so?

Mr. GILES. I purposely did not bring a list of them with me.

Mr. KLEINFELD. For what purpose?

Mr. GILES. I didn't want to get involved in any arguments about the thing. I didn't bring the list with me; that is all. I can mail a list if this committee requires it.

Mr. KLEINFELD. I would request that you do so. I think we would keep it confidential.

The CHAIRMAN. It is not for publication. As a matter of fact, we don't intend to print any of these.

Mr. GILES. I can tell you exactly what they are.

The CHAIRMAN. We want to know the important ones.

Mr. GILES. In confidence, we have a reason for not giving it. I would give you that reason if you wish.

The CHAIRMAN. If you want to give your reason, we will make it part of the record, certainly.

Mr. KLEINFELD. What is the reason?

Mr. GILES. Well, I am sure that a lot of leaders in the cosmetic industry are using these things, but some of these things—we have found out that certain proportions of things prevent what we call sweating of oil in hot weather on a face cream, for example, and I don't think that all the cosmetic industry knows that.

The CHAIRMAN. We don't want your trade secrets, of course. We just want to know for our own information what the ingredients are.

Mr. GILES. I can supply them to the committee.

Mr. KLEINFELD. We did not ask for any quantitative formulas, we just asked for the names of the ingredients.

Mr. GILES. I understand that. And if it is a trade name, who the manufacturer is, do you want that?

Mr. KLEINFELD. We will leave it to your judgment. We want the names of the ingredients.

Mr. GILES. And that will be in confidence?

Mr. KLEINFELD. That is what the chairman said; yes.

If the law were amended to require that your ingredients be set forth on your labels, do you believe that would give away your trade secrets?

Mr. GILES. I don't think it would, sir.

Mr. KLEINFELD. That is all we are asking you for—the names of your ingredients.

Mr. GILES. Active ingredients, you mean?

Mr. KLEINFELD. All ingredients, without indicating any quantities or proportions.

Mr. GILES. Maybe I didn't understand your question.

Mr. KLEINFELD. Suppose the law were amended to require that each cosmetic manufacturer was required to put on his label the names of all the ingredients contained in his products.

Mr. GILES. Then we would have to go along, that is all.

Mr. KLEINFELD. Do you think it would put you out of business?

Mr. GILES. No.

Mr. KLEINFELD. Mr. Chairman, I would like to have this document marked for identification.

The CHAIRMAN. It will be marked for identification. What number?

Mr. KLEINFELD. Make it No. 2.

(The document referred to was marked "No. 2" for identification and will be found in the files of the committee.)

Mr. KLEINFELD. Doctor, I show you this pamphlet marked No. 2 for identification and ask you whether it refers to a product made by your company.

Mr. GILES. No, sir. It is stated in here that it is imported from France.

Mr. KLEINFELD. That product is not handled by your company at all?

Mr. GILES. We sell it.

Mr. KLEINFELD. You sell it?

Mr. GILES. It is referred to in the context.

Mr. KLEINFELD. Is that advertising literature gotten up by your company?

Mr. GILES. Yes, sir.

Mr. KLEINFELD. This product is called—and please tell me if I pronounce it correctly—Le Secret de Blanche Delysia. Is this made of horse serum?

Mr. GILES. Yes.

Mr. KLEINFELD. Do you know how this horse serum is obtained?

Mr. GILES. I have part of the contract which we signed with that company.

Mr. KLEINFELD. I merely ask whether you know——

Mr. GILES. To my knowledge I do not.

The CHAIRMAN. That is the answer.

Mr. KLEINFELD. And you import it from France; is that correct?

Mr. GILES. That is right.

Mr. KLEINFELD. And you sell it?

Mr. GILES. Yes.

Mr. KLEINFELD. And you get out this advertising material?

Mr. GILES. Our company gets out the advertising.

Mr. KLEINFELD. This advertising pamphlet says this in part:

Now! From Gay Paree comes one of the most revolutionary beauty treatments of all times. It's called Le Secret de Blanche Delysia after the fabulous French beauty who developed it from an ancient beauty ritual which was closely guarded for centuries.

Le Secret comprises seven magic little vials which hold a true natural beauty serum for aging skin. And what woman over 40 isn't beset by this most insidious bug-a-boo!

For years there were rumors in this country about Le Secret. Some American women traveling abroad returned and were openly chided by their friends as having a "face lift"—so amazing was the improvement in the appearance of their skin. These women had merely discovered Le Secret in Paris and their complexions were ravishingly lovely—fresher, younger, and firmer looking than in years.

Then Primrose House thoroughly investigated Le Secret and is now importing it direct for you. It's simply a must for women who want to keep their skin looking youthful and alive!

What kind of investigation did you make of those claims?

Mr. GILES. First, we had one of the leading biological laboratories in the country, which is located there in Indianapolis, to test it and determine whether it was what it was represented to be. I mean whether it was horse serum, normal sterile horse serum. That part I know, because I was in on the conversation.

Mr. KLEINFELD. You know it is horse serum?

Mr. GILES. What?

Mr. KLEINFELD. You know it is horse serum?

Mr. GILES. I know that is what these people said it was. I am not in position to say that, but that was done.

Secondly, I ran 25 patch tests on this horse serum and a similar bovine serum, and I got no negative results whatsoever—I mean no bad results. I have run enough patch tests to know what erythema looks like.

Then we tried it out on a hundred customers who bought it. It is an expensive thing. And they bought it, and they have a telephone number, and we took their names on a card, and then we went to them afterward with a questionnaire, and it was loaded, so we got the facts that we wanted. Some of them bought it again and none of them said it did them any damage.

The CHAIRMAN. I have difficulty in hearing you, Doctor. Please keep your voice up.

Mr. GILES. All right.

Mr. KLEINFELD. And it comes in boxes of seven vials sold for $12?

Mr. GILES. There is also a box of 26 vials that sells for $36, plus $7.20 tax.

Mr. KLEINFELD. Did you make any chemical analysis of this horse serum, this product, to find out what was in it?

Mr. GILES. You just asked me that. I told you this biological laboratory assayed it for us.

Mr. KLEINFELD. Did you also investigate to find out whether it would in fact make women ravishingly lovely, fresher, younger, and firmer looking?

Mr. GILES. The only evidence we have is the good portion that buy it again. They found it was not harmful.

Mr. KLEINFELD. Do you think it will do all that you claim for it, as a scientist?

Mr. GILES. A scientist is different from a copywriter.

Mr. KLEINFELD. I know that is true. [Laughter.] Go on from there.

Mr. GILES. I know that the product has an astringent effect if applied, because I have used it myself.

Are the directions on there how to use it? I don't know. But anyhow——

Mr. KLEINFELD. Yes, it says this:

One vial of this secret is applied every day for 5 days. Then one application every other day for a week. During the next 2 weeks, twice a week. Notice the delightfully bracing, firming, lifting feeling. Notice how it helps smooth out those horrid aging surface lines and wrinkles. The frequency of use thereafter depends on your own judgment and how long your skin is benefited by the last application. Most women, after obtaining the desired results, find only one application a week sufficient to keep their skin enchantingly lovely, youthful, and firm in appearance. You must remember, too, that if your skin has been neglected for a long time—naturally it will take a little longer for Le Secret to work.

Those are the directions you mean?

Mr. GILES. Yes.

Mr. KLEINFELD. I have nothing else.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. No questions.

The CHAIRMAN. Mr. Horan?

Mr. HORAN. Could this product that the counsel is asking you about, Mr. Giles, be produced synthetically?

Mr. GILES. I don't know the ingredients in horse serum. I am not a biological chemist. I am an organic chemist.

Mr. HORAN. Is not this an organic product?

Mr. GILES. It is of biological origin.

Mr. HORAN. We are not prosecuting anybody. We are just trying to get at some of the facts in the case so we can make some recommendations to Congress.

Mr. GILES. I see.

Mr. HORAN. Certainly your company is not on trial here. We are just asking questions.

Mr. GILES. I see

The CHAIRMAN. That is all. Thank you.

Any further questions, Mr. Kleinfeld?

Mr. KLEINFELD. No other questions.

The CHAIRMAN. You are excused.

Mr. GILES. Is that all, sir?

The CHAIRMAN. That is all.

Any other witnesses, Mr. Kleinfeld?

Mr. KLEINFELD. No.

The CHAIRMAN. That will conclude the hearings in New York for the present. I do not know whether we will have any more hearings in the city of New York.

We are indebted to the judges for the use of the court rooms.

And I want to pay a special compliment to our reporter, Mr. Veley. I know you have been on the job very long, and I want to compliment you highly. You have been especially diligent and have done an exceptionally fine job.

The committee will now recess.

(Whereupon at 3 p. m. the committee recessed.)

CHEMICALS IN FOODS AND COSMETICS

TUESDAY, JANUARY 29, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong. 1st sess. continuing the investigation, and study begun under authority of H. Res. 323, 81st Cong. 2d sess.), at 10 a. m., in room 445, Old House Office Building, Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney of New York, Miller of Nebraska, and McDonough of California.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will come to order.

Mr. Kleinfeld, call the first witness.

Mr. KLEINFELD. Dr. Hueper.

The CHAIRMAN. Your name and address, Doctor?

Dr. HUEPER. Wilhelm C. Hueper, 8495 Rockville Pike, Bethesda, Md.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF WILHELM C. HUEPER, M. D., BETHESDA, MD.

Mr. KLEINFELD. Dr. Hueper, you are a medical doctor?

Dr. HUEPER. Yes; I am.

Mr. KLEINFELD. When and where did you get your medical degree?

Dr. HUEPER. I graduated from the University of Kiel, Germany, 1920.

Mr. KLEINFELD. What is your special field of professional interest?

Dr. HUEPER. My special field of professional interest is pathology.

Mr. KLEINFELD. Are you a diplomate of the American Board of Pathology?

Dr. HUEPER. Yes; I am.

Mr. KLEINFELD. Please tell the committee what pathology is.

Dr. HUEPER. It is that branch of medicine which deals with the essential nature of disease, especially with the structural and functional changes which cause disease or which are caused by disease.

Mr. KLEINFELD. And you have been engaged in this work in various hospitals both in this country and abroad?

Dr. HUEPER. Yes; I have.

Mr. KLEINFELD. Have you been employed by various private and public research institutions in the field of pathology?

Dr. HUEPER. Yes. From 1921 to 1923, I was employed in the Pathological Institute of a Municipal Hospital in Berlin.

Between 1924 and 1930, I was pathologist and director of laboratories of Mercy Hospital, the main teaching hospital of Loyola University Medical School in Chicago, where I also served as associate professor of pathology during that period.

From 1930 to 1934, I was chief pathologist of the Cancer Research Laboratories of the University of Pennsylvania in Philadelphia, and pathologist at the American Oncologic Hospital in Philadelphia.

From 1934 to 1938, I was assistant director of the Haskell Laboratory of Industrial Toxicology of the du Pont Co. in Wilmington.

From 1938 to 1948, I was the assistant director of the Institute for Therapeutic Research of the Warner Co. or Pharmaceutical and Cosmetic House in New York, and in 1948 I was invited to join the staff of the National Cancer Institute to head the new section of Environmental Cancer and to head the research laboratories of an experimental study of environmental cancer.

Mr. KLEINFELD. Are you a member of the Subcommittee on Malignancy of the National Research Council?

Dr. HUEPER. Yes; I am.

Mr. KLEINFELD. Have you published any papers which appeared in the scientific literature?

Dr. HUEPER. I have published through the years around 200 papers, about a hundred dealing with cancer.

Mr. KLEINFELD. And are you the author of a book on cancer?

Dr. HUEPER. Yes; I am. I have prepared a book entitled "Occupational Tumors and Allied Diseases," which was published in 1942 by C. C. Thomas, Springfield, Ill.

Mr. KLEINFELD. To recapitulate, how long have you specialized in the field of cancer research?

Dr. HUEPER. One of my first publications in the early 1920's dealt only with cancer of the lung and with changes produced in the human tissue by paraffin, but my more serious interest in cancer dates from 1930, when I joined the University of Pennsylvania.

Mr. KLEINFELD. Mr. Chairman, may I suggest that Dr. Hueper's biography be inserted in the record to save some time.

The CHAIRMAN. All right.

(Biography of Wilhelm C. Hueper, M. D., is as follows:)

Age: 56
1894: Born Schwerin, Germany
1913–14: Studied medicine, University of Marburg, Germany
1914; 1918–19: University of Rostock, Germany
1919–20: University of Kiel, Germany
1920: Medical degree, University of Kiel, Germany
1924: State board examination for license, Illinois
1929: Naturalized 1929, Illinois
1920: Voluntary assistant physician, Gynecologic Clinic, University of Kiel
1920–21: Assistant physician, Evangelisches Diakonissenkrankenhause, Witten; surgery
1921–23: Assistant physician, Pathological Institute, Auguste Viktoria Krankenhaus, Berlin
1923–24: Resident physician, Evangelical Deaconess Hospital, Chicago, Ill.
1924–30: Pathologist and director of laboratories, Mercy Hospital, Chicago, Ill.; Associate professor of pathology, Loyola University School of Medicine, Chicago, Ill.
1930–33: Chief pathologist, Cancer Research Laboratories, University of Pennsylvania, Philadelphia; pathologist, American Oncologic Hospital, Philadelphia.

1933–34: Resident pathologist and research assistant, department of pathology, University Hospital, University of Pennsylvania, Philadephia.
1934: Director of laboratories, Uniontown Hospital, Uniontown, Pa.
1934–38: Assistant director and pathologist, Haskell Laboratory of Industrial Toxicology, du Pont Co., Wilmington, Del.
1938–48: Assistant director and principal pathologist, in charge of pathology, pharmacology, roentgenology, bacteriology research, Warner Institute for Therapeutic Research, New York.
1948: Chief, Cancerigenic Studies Section (environmental cancer) Chief, Cancerigenic Research Laboratory.

PROFESSIONAL OFFICES AND MEMBERSHIPS

Diplomate, American Board of Pathology: Pathologic anatomy
Charter member and first president, American Society for the Study of Arteriosclerosis
Associate fellow, American Medical Association
Fellow, New York Academy of Science (honorary)
Fellow, American Association for the Advancement of Science (honorary)
Chairman, registry committee, Gerontological Society, Inc.
Member, Subcommittee on Malignancy, National Research Council (chemical carcinogenesis)
Charter member, committee on industrial cancer, Department of Labor, New York
Chairman of the session on occupational tumors, International Congress of Cancer Research, St. Louis, September 3–7, 1947
Coordinator of the round table on environmental cancer, National Cancer Conference, Memphis, 1949

MEMBER OF THE FOLLOWING ORGANIZATIONS

American Association of Pathologists and Bacteriologists
American Society of Experimental Pathology
American Association of Cancer Research
American Medical Directors Association
American Association for the Advancement of Science
American Heart Association, member of assembly
New York Academy of Science
American Society for Gerontology
American Industrial Hygiene Association
American Public Health Association
Public Health Cancer Association of America
Cancer Prevention Committee, Inc.
Washington Society of Pathologists

Mr. KLEINFELD. Dr. Hueper, what is your present position?

Dr. HUEPER. I am Chief of the Cancerigenic Studies Section of the Cancer Control Branch of the National Cancer Institute, and the Chief of the Cancerigenic Research Laboratories of the Cancer Research Branch of the National Cancer Institute.

Mr. KLEINFELD. How long have you been associated with the Public Health Service?

Dr. HUEPER. Since April 1, 1948.

Mr. KLEINFELD. Is it part of your present position to be familiar with the literature concerning cancer research?

Dr. HUEPER. I am trying to keep up with the cancer literature as far as it concerns cancer epidemiology and cancer causation, and I try to obtain a good working knowledge of all other aspects of cancer.

Mr. KLEINFELD. Doctor, are you in personal communication with many other individuals and organizations engaged in cancer research both in this country and abroad?

Dr. HUEPER. Yes; I maintain rather extensive connections with official and private organizations and individuals working in the field of

cancer. As far as governmental agencies are concerned, I keep in contact with the work of the Food and Drug Administration.

I am conducting, in conjunction with the Bureau of Mines, at present a study of the shale oils and synthetic oils produced from coal as far as possible cancerigenic properties are concerned.

I have occasional contact with our Navy Department, with the Department of Agriculture.

I have served as a consultant for the Department of Labor for cases of claims made by Government employees on accidental and occupational cancer for compensation against the Federal Government.

Mr. KLEINFELD. Dr. Hueper, is it not a fact that during these many years when you have been engaged in cancer work you have spent a considerable amount of time actually in the laboratories?

Dr. HUEPER. Yes. My main scientific work, as is apparent from my bibliography, was experimental work. I have done experimental work not only on cancer but on various other aspects of human disease; for instance, especially in arteriosclerosis.

Mr. KLEINFELD. In what capacity are you testifying here today, Doctor?

Dr. HUEPER. I am testifying as a private citizen, basing my testimony on the experiences and training I have had during the last 25 years.

Mr. KLEINFELD. You are not appearing today on behalf of any agency or bureau of the United States Government?

Dr. HUEPER. I do not think so.

Mr. KLEINFELD. Nor on behalf of any private organization?

Dr. HUEPER. I don't think so.

Mr. KLEINFELD. You have been concentrating, Doctor, in recent years on the problem of environmental cancer; have you not?

Dr. HUEPER. I have worked on environmental cancer for about 20 years, but my exclusive interest in environmental cancer dates from 1948.

Mr. KLEINFELD. Are you the author of a 69-page booklet entitled "Environmental and Occupational Cancer," supplement 209, Public Health Reports, 1948, Federal Security Agency, Public Health Service?

Dr. HUEPER. Yes; I am.

Mr. KLEINFELD. And are you the author of a booklet entitled "Environmental Cancer," published by the Federal Security Agency, Public Health Service?

Dr. HUEPER. Yes.

Mr. KLEINFELD. And are you the author of a 37-page booklet entitled "A Methodology for Enviromental and Occupational Cancer Surveys," Public Health Technical Monograph No. 1, Federal Security Agency, Public Health Service?

Dr. HUEPER. Yes.

Mr. KLEINFELD. Doctor, in your opinion, is the incidence of cancer presently increasing?

Dr. HUEPER. The number of cancer cases is still on the increase, but that increase is mainly due to the increase in population and the increase of the older-age groups in our population. The absolute number of cancer per, let's say, 100,000 of population has remained stationary since 1940, but there are some cancers which have increased

during the past years; that is especially cancer of the lungs and leukemias.

I have here a chart which shows the increase in cancer of the lung, which I may pass around, which shows the rather spectacular increase of cancer of the lung in males during the past two decades.

Dr. MILLER. At that point, Doctor, would you say that might also be due to the ability of the scientific profession to discover cancer?

Dr. HUEPER. To a minor degree, yes; I would think so; but the increases are so spectacular they cannot all be attributed to that.

Dr. MILLER. What method did they have 20 years ago to discover cancer of the lungs?

Dr. HUEPER. The second paper I ever published, 25 years ago, was on the increase of lung cancer in Germany, and at that time we already noted from post-mortem records that practically everywhere there was an increase in the incidence rate of cancer of the lung.

Dr. MILLER. When you and I were medical students, how many cases of cancer of the lung did you see?

Dr. HUEPER. I saw quite a bit on the autopsy table.

Dr. MILLER. They were not diagnosed, however.

Dr. HUEPER. We were posting about 95 percent of our patients who died in the hospital for many years, so we had a pretty good record of who died from cancer of the lungs.

Mr. KLEINFELD. Mr. Chairman, may I suggest that this chart be included in the record?

The CHAIRMAN. Without objection, we will put it in.

(The chart referred to follows on p. 1358)

Mr. KLEINFELD. Dr. Hueper, is it true that approximately one-half of all cancer observed in the male is cancer of the alimentary system?

Dr. HUEPER. In the United States, approximately it is that way.

Mr. KLEINFELD. And what do you mean by the alimentary system, Doctor?

Dr. HUEPER. The alimentary system includes the esophagus, the stomach, the small intestine, and the large intestine down to the anus.

Mr. KLEINFELD. In what part of the female body, Doctor, does cancer appear most frequently?

Dr. HUEPER. The breast is the most frequent site of cancer in the female. But these figures only go for mortality figures, not for morbidity figures. The most frequent cancer is cancer of the skin, if we deal with morbidity figures, but skin cancer is cured to a very high degree. About 75 to 95 percent of all skin cancer is cured, so those cancers won't appear in our mortality figures.

Mr. KLEINFELD. Leaving aside skin cancer, in what part of the female body does cancer appear next most frequently after cancer of the breast?

Dr. HUEPER. The uterus. But again I might point out those ratios only go for the United States. They vary in different countries considerably.

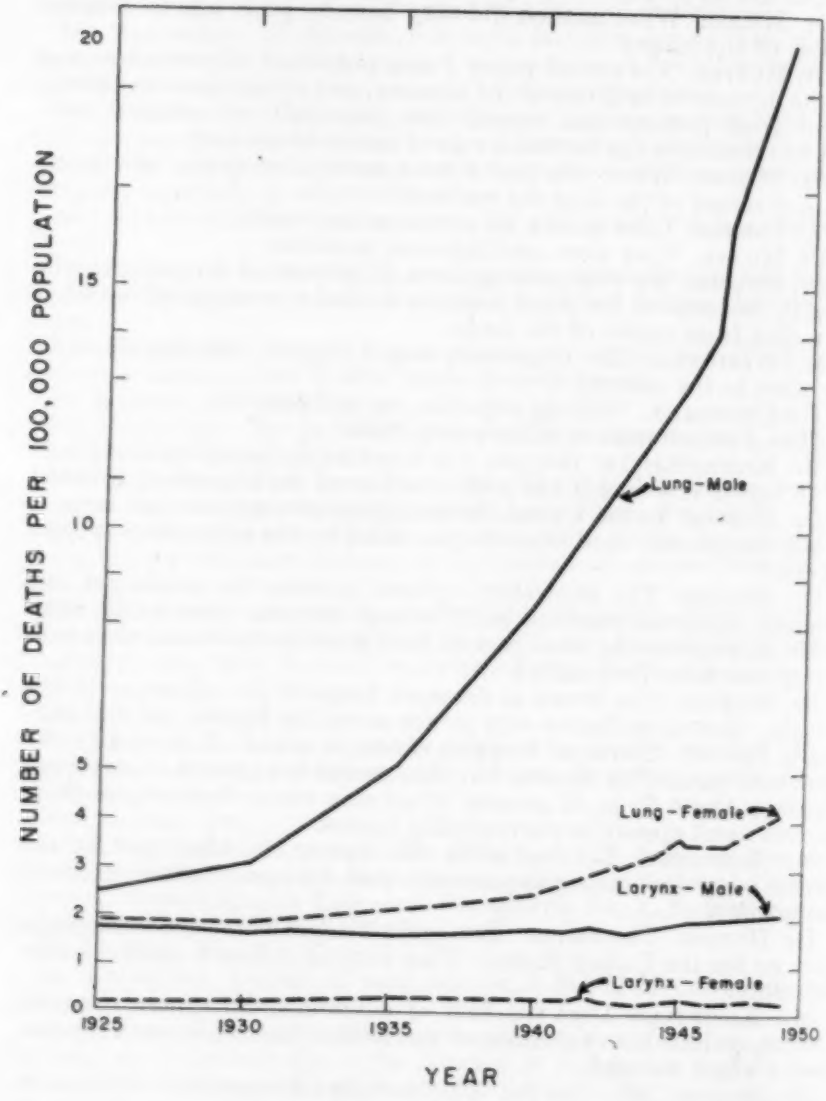
Mr. KLEINFELD. Does the field of environmental cancer research, Doctor, include the evaluation of the foods which we eat and the cosmetics which we use?

Dr. HUEPER. Yes; they do. They include all exogenous carcinogenic agents, inanimate and animate, which may cause cancer, all agents chemical and parasitic.

Mr. MCDONOUGH. Why do you emphasize the incidence of cancer of the lung in the male over the female?

TRENDS IN RESPIRATORY CANCER MORTALITY 1925–1948

TREND IN MORTALITY FROM RESPIRATORY CANCER, LUNG COMPARED WITH LARYNX, BY SEX, 1925–1948



Dr. HUEPER. The reason for this marked discrepancy is not definitely known. It may be that environmental agents act on the male organism more often and more intensely, that those agents are responsible.

Mr. MCDONOUGH. You mean occupational hazards?

Dr. HUEPER. Yes.

Mr. MCDONOUGH. That women are not subject to but that men are?

Dr. HUEPER. That is right. But that would provide only a partial explanation. I do not think that will provide the total explanation, not by any means.

Mr. MCDONOUGH. Is there any organic difference in the male and female lung that could bring about this condition?

Dr. HUEPER. Not that we know. You probably know that the question of whether the increase in the smoking of cigarettes during the past decades has been raised and to what extent it is responsible for an increase in cancer in the lung is a subject of very lively discussion and subject of very serious controversy.

Mr. MCDONOUGH. You are not saying it is the cause?

Dr. HUEPER. Oh, no.

Mr. MCDONOUGH. As a matter of fact, women smoke as much as men do.

Dr. HUEPER. They started to do that now, but you have to consider that a long latent period elapses between the start of exposure to carcinogenic agents and the appearance of the cancer. It can take anywhere between 5 and 50 years before a cancer can become manifest after an exposure starts. It is one of the difficult aspects of studies in environmental cancer. So the women have not started long enough to smoke cigarettes wholesale.

Mr. MCDONOUGH. What would you say is the cause of cancer that brings about evidence quickest? What shows cancer the quickest?

Dr. HUEPER. What agents?

Mr. MCDONOUGH. Yes.

Dr. HUEPER. A very powerful agent which can produce cancer within 2 years is a dye intermediate called betanaphthylamine.

Mr. KLEINFELD. Betanaphthylamine?

Dr. HUEPER. Yes; a naphthalene derivative with an amino group.

Mr. KLEINFELD. How would the average individual be exposed to that?

Dr. HUEPER. By inhalation, skin contact, and ingestion. Anything which we inhale, we also ingest, so there is an ingestion factor present.

Mr. KLEINFELD. You mean to say if a person is exposed to that particular chemical——

Dr. HUEPER. That is right.

Mr. KLEINFELD (continuing). He would be more likely to show cancer?

Dr. HUEPER. Cancer of the bladder, a very specific cancer.

Mr. KLEINFELD. A very specific cancer?

Dr. HUEPER. Yes.

Mr. KLEINFELD. Dr. Hueper, would you say that considerable research has been done on the possible relationship between chemicals in food and cosmetics and cancer?

Dr. HUEPER. I think a limited amount of research has been done in this country and abroad on such aspects.

Mr. KLEINFELD. Can you tell the committee why, in your opinion, more work has not been done in an important field such as that?

Dr. HUEPER. Work in that particular field is rather complex and requires rather large funds, facilities, and trained personnel, and under the present conditions is not very rewarding for the private investigator.

Mr. KLEINFELD. Do you think that it is advisable or necessary that more work should be done in that field?

Dr. HUEPER. I think so; yes. Quite extensive work should be done on that.

Mr. KLEINFELD. Some work has been done on occupational or industrial cancer, has it not?

Dr. HUEPER. Yes; quite a bit of clinical as well as experimental work has been done on occupational cancer. The reason for this is the fact that occupational cancers are so much more obvious. They occur in restricted groups of workers. One can trace the etiology very much easier, and they represent for the industry affected a serious problem, and therefore some work is done on that phase.

Mr. KLEINFELD. Would you say that there is a relationship between the work done in occupational cancer and the field of chemicals in foods and cosmetics?

Dr. HUEPER. Yes; there is a relatively close relationship in many respects, because the agents which cause occupational cancers may be in part identical, in part similar, to agents which possibly may be present in our food, drugs, and cosmetics.

Mr. KLEINFELD. Mr. Chairman, I would like this pamphlet marked "Exhibit A" for identification.

The CHAIRMAN. It will be so marked.

(The pamphlet referred to was marked "Exhibit A" and will be found in the files of the committee.)

Mr. KLEINFELD. Dr. Hueper, this pamphlet marked "Exhibit A" for identification is entitled "A Methodology for Environmental and Occupational Cancer Surveys," by W. C. Hueper, M. D., Public Health Technical Monograph No. 1, Federal Security Agency, Public Health Service. That was prepared by you?

Dr. HUEPER. Yes.

Mr. KLEINFELD. On pages 33 to 36 of the monograph, appendix C, entitled "Occupational Hazard Code," there appears a list of numbered substances, some of which have asterisks next to them, and at the bottom of the page are the words "Carcinogenicity recognized or suspected." Is that correct?

Dr. HUEPER. That is right.

Mr. KLEINFELD. Numbers 142 and 143 on that list are aniline dyes, including aniline and other amine compounds of benzol and its homologues. Are these suspected or recognized as being carcinogenic?

Dr. HUEPER. Well, the substances used in the production of aniline dyes, or some of the aniline dyes, are recognized as well as suspected carcinogenic chemicals. There are aniline dyes for which we have definite evidence that they are carcinogenic to animals. That is to animals, not to man.

Mr. KLEINFELD. In your opinion, Doctor, can it be said that it is reasonably certain at this time that these aniline dyes are completely safe from the cancer viewpoint?

Dr. HUEPER. If you are talking about the aniline dyes which are certified by the Food and Drug Administration, I think that the evidence we have makes them reasonably safe for general use, with perhaps, from my personal viewpoint, doubts for a few of the dyes.

Mr. KLEINFELD. With doubts on a few of the dyes that have been certified?

Dr. HUEPER. Yes.

Mr. KLEINFELD. Dr. Hueper, there has been published some cancer research work recently concerning light green S. F.?

Dr. HUEPER. That is right.

Mr. KLEINFELD. Are you familiar with that work?

Dr. HUEPER. I am familiar with that.

Mr. KLEINFELD. Can you explain that to the committee, please?

Dr. HUEPER. Light green S. F. was studied first by Schiller in this country through injection into rats, and he obtained in an appreciable number of animals cancers at the site of injection. That work was checked later on by Harris, a member of the Eli Lilly staff who substantiated that finding, and I think it was later on checked by the members of the staff of the Food and Drug Administration who also got development of cancer at the site of injection when injected into rats, but they were unable to produce any cancer when the dye was fed.

Mr. KLEINFELD. Is this light green S. F. part of a group which had been previously suspected as producing cancer?

Dr. HUEPER. No, it had not. It is still a rather puzzling observation, because the dye is not included in the group of dyes which we usually connect a suspicion of carcinogenicity.

Mr. KLEINFELD. Do you know whether light green S. F. is presently used in foods?

Dr. HUEPER. It is one of the certified dyes.

Mr. KLEINFELD. So there are a number of the certified dyes presently in use in food and cosmetics of which you think there is now some suspicion; is that correct?

Dr. HUEPER. Well, definite evidence as far as their carcinogenicity is concerned in regard to rats.

Mr. KLEINFELD. And the fact that some of these dyes, particularly light green S. F., may have produced cancer in experimental animals does not necessarily mean, as I understand you, that it will produce cancer in man?

Dr. HUEPER. No; it does not mean that at all.

Mr. MCDONOUGH. I did not get that.

Mr. KLEINFELD. The fact that some of these colors, particularly light green S. F., may have produced cancer in experimental animals does not necessarily mean they will produce cancer in man?

Dr. HUEPER. That is right; it does not mean that at all.

The CHAIRMAN. The answer is "Yes" to his question?

Dr. HUEPER. That is right.

Mr. MCDONOUGH. As I understand it, you say the experiments show the injection of this into rats caused cancer at the——

Dr. HUEPER. Site of injection.

Mr. MCDONOUGH. At the site of injection?

Dr. HUEPER. Yes.

Mr. MCDONOUGH. But it did not cause cancer through ingestion?

Dr. HUEPER. That is right.

Mr. McDonough. Have there been any experiments in an attempt to inject light green S. F. into man?

Dr. Hueper. I do not think I would volunteer for that experiment. [Laughter.]

Mr. McDonough. I understand. In other words, you don't know that it will or will not?

Dr. Hueper. That is right. I only say we don't know that. But it is not necessary that the dye is carcinogenic to man. The evidence that a carcinogenic substance, cancer-producing substance, produces cancer in animals does not mean that the same substance will produce cancer in man or in any other species.

To translate that in somewhat more general terms, the agents which are able to cause cancer in animals, including man, are as species specific in their action as microorganisms are in producing diseases. We cannot produce with the same microorganism disease in all species.

Mr. Kleinfeld. In other words, Doctor, if a particular substance will produce cancer in one species of animal, you say it doesn't necessarily follow that it will produce cancer in man?

Dr. Hueper. That is right.

Mr. Kleinfeld. You don't know, do you, whether it will or not?

Dr. Hueper. No; it remains an open question.

Mr. Kleinfeld. But you are a little suspicious of it; are you not?

Dr. Hueper. I would look upon a substance of that sort with some doubt. I wouldn't like that substance for human consumption.

Mr. Kleinfeld. Dr. Hueper, can we be reasonably certain, in the light of the experiments of which you spoke, that light green S. F. will not produce cancer in man?

Dr. Hueper. I don't think we know that.

Mr. Kleinfeld. You don't know that it will, and you don't know that it won't?

Dr. Hueper. No; I don't think so. It is entirely open.

Mr. Kleinfeld. If it is entirely open, and since we are talking about cancer, what do you think we ought to do about light green S. F. from your viewpoint as a scientist?

Dr. Hueper. Expressing, again, only my personal opinion, I feel that foresight is better than hindsight, and I think I would approach the dye manufacturers to replace light green S. F. by another green dye which has no carcinogenic stigmata. I would rather stay on the safe side of the deal.

Mr. Kleinfeld. Doctor, do you think that these dyes are essential to our food or cosmetic supply?

Dr. Hueper. Well, they are not serving any useful purpose except eye appeal.

Mr. Kleinfeld. Dr. Hueper, we have been informed that recently in Germany some action was taken with respect to the use of certain coal-tar dyes and that such action was intended to make the use of such dyes safer; is that correct?

Dr. Hueper. That is right.

Mr. Kleinfeld. Could you explain what was done in Germany and why it was done?

Dr. Hueper. The German Research Council has a special committee on the drafting of new legislation for food colors or dyes, and they have come up with a new list of permitted dyes. The list is broken down into two categories. One, of fourteen dyes, contains those dyes which are permitted without any restriction. Then they have a list

of, I think, another seven or eight dyes for which permission has been given only temporarily. Those dyes are still under investigation, whether they should be permitted permanently.

Mr. KLEINFELD. Were some changes made in the chemical structure of certain of these dyes?

Dr. HUEPER. Yes. I had some correspondence with members of the German Research Council on that point. They approached me on it. And as a result of this correspondence they modified two dyes. In our list these are yellow A. B. and yellow O. B. The dyes are derivatives of beta-naphthylamine, and the possibility exists that the dye may be broken down in the human body in such a way that beta-naphthylamine may be liberated. The dyes have been tested on rats, again, here in this country, as well as in Germany. They have not produced cancers in rats.

But, nevertheless, the Germans felt there was a possibility that they might produce cancers in human beings, and what they have done is this: They have attached to the beta-naphthylamine component of the dye, as well as to the other component, which is the amino benzol component, the sulfonic acid group. Because we know from experience from the dye industry, as well as experimental work with various dyes, that an attachment of sulfonic acid groups to the benzol amines will destroy the carcinogenic properties of such dyes. So what they have done is, they have covered all benzol amines in the dye with sulfonic acid groups.

Mr. KLEINFELD. Doctor, did you testify a few minutes ago that beta-naphthylamine had produced cancer of the bladder frequently in industrial workers?

Dr. HUEPER. Yes; it is one of the most important observations we have from a cancer viewpoint.

It was first made in 1895 by the German dye industry, and then that cancer has traveled everywhere including our own country where dye industries have been established. The first observations in our country dates from 1932 when the du Pont Co. discovered that they had 23 workers with bladder cancer among their dye intermediate operators. And we have approximately in this country now—approximate, we have no definite figures on it—250 cases of bladder cancer in dye workers for which we can trace the etiology. We have more, but that is the number we can trace. There are more than a thousand cases on record from all countries.

I have worked on that experimentally, and if the members want to see cancers of the bladder in dogs which were fed beta-naphthylamine, there are two pictures of the bladders of two dogs [showing pictures].

Mr. MCDONOUGH. That is through the digestive system?

Dr. HUEPER. That is right.

Mr. MCDONOUGH. And located in the bladder?

Dr. HUEPER. Only the urogenous tracts were involved. The carcinogenic agent is apparently excreted with the urine, and that mechanism accounts for the localization of these tumors mainly in the bladder. Occasionally they occur in the renal pelvis or pelvis of the kidney.

Mr. KLEINFELD. Is it not a fact we are presently using those dyes—yellow A. B. and O. B.—in our food and cosmetic supplies today?

Dr. HUEPER. Without question, yes; we do.

Mr. KLEINFELD. Without the changes made by the Germans?

Dr. HUEPER. There are no sulfonic-acid groups on those.

Mr. KLEINFELD. We have not made those changes, have we?

Dr. HUEPER. We have not made those changes; no.

Mr. KLEINFELD. Was the change which was made by the Germans effected in an attempt to minimize the possible hazard which may result from the use of the dyes?

Dr. HUEPER. Yes. It was really made mainly on theoretical grounds, because we have no evidence, as I said already, that the dyes are actually carcinogenic in man. But to be on the safe side of the matter they modified the dye by adding sulfonic-acid groups. That was the only reason for modifying the dyes.

Mr. KLEINFELD. Would you have been in favor of such change?

Dr. HUEPER. I think so. That is advisable.

Mr. MCDONOUGH. What change would the addition of a sulfonic-acid group have?

Dr. HUEPER. I beg your pardon.

Mr. MCDONOUGH. What change did that have on the beta-naphthylamine?

Dr. HUEPER. You get beta-naphthylamine sulfonate, and that sulfonate, if it is given to dogs, does not produce cancer, and workers who handle beta-naphthylamine sulfonate have no bladder cancer. That is the evidence. In fact, the German, Swiss, and English dye industry have discontinued making the beta-naphthylamine because they cannot control the hazards. They have tried that for many years but beta-naphthylamine cancer still occurred among their dye workers, although they introduced extensive precautionary measures. So what they are doing now—they sulfonate the beta-naphthol before they aminize it. So there never is free beta-naphthylamine present in the operation.

Mr. MCDONOUGH. In other words, the cancer-producing material is beta-naphthylamine?

Dr. HUEPER. That is right; at least that is what we think right now.

Mr. MCDONOUGH. And not the ammonium salts?

Dr. HUEPER. No.

Mr. MCDONOUGH. And then you neutralize that with sulfonic acids?

Dr. HUEPER. With sulfonic acid groups.

Mr. MCDONOUGH. In doing that do you neutralize the ammonia?

Dr. HUEPER. I don't think it has anything to do with ammonia. It has probably something to do with the special configuration of the molecules which destroys the carcinogenic action.

You see we have from experience with other carcinogenic aromatic compounds, like the benzanthracines—we have experience that if we shift side chains of the carcinogenic hydrocarbon, let us say, from the 8 to position 12 in the ring, we may destroy the carcinogenic action of it, the action is so specific as far as the special arrangement is concerned.

Also if one lengthens the side chain beyond a certain size, one destroys the carcinogenic property of the compound. Why that is, we only speculate about.

Mr. MCDONOUGH. Is the cancer which is caused by the beta-naphthylamine contagious?

Dr. HUEPER. No. Cancer is not contagious as far as produced by chemical or physical agents; if you come in contact with the chemical agent, you will get it.

Mr. MCDONOUGH. If you come in contact with any excretion from the individual who has it, would you get it?

Dr. HUEPER. That has been tried recently. English workers—Dr. Bonser in England isolated from the urine of dye workers a metabolite of beta-naphthylamine 2 amino 1 naphthol and introduced that into the bladder of rats and produced cancer with that metabolite.

I mentioned that experiments on rats using aromatic amines are not always very conclusive because rats do not react with cancer to beta-naphthylamine at least. So if we have a beta-naphthylamine compound and try that on rats, the negative result does not mean very much.

Dr. MILLER. One question. The sulfonic acid group, how long has that been used by the Germans?

Dr. HUEPER. Very recently. I think perhaps 4 or 5 years.

Dr. MILLER. Do you think the time has been sufficiently long to establish whether there will be any cancer or not?

Dr. HUEPER. No.

Dr. MILLER. Because of the sulfonic acid groups?

Dr. HUEPER. Whenever such precautionary measure is established, it takes at least 10 years to be certain—halfway certain—that the measure is effective.

Dr. MILLER. Then you would not want to say here that just because we use the sulfonic acid change it might not still have a carcinogenic effect?

Dr. HUEPER. I think they have better evidence than just that. They have the evidence from their own operations that they have no bladder cancer among the workers who handled the sulfonated compound.

Dr. MILLER. And you think 5 years is sufficient time to determine that?

Dr. HUEPER. They used them all the time. See, in production of many of the dyes they used sulfonated naphthylamine, so they had practical experience with that compound before.

Dr. MILLER. That is all.

Mr. MCDONOUGH. One other question. How does the worker handling beta-naphthylamine get it into his system? Does he breathe it?

Dr. HUEPER. He breathes it in, he has skin contact with it. And anything we inhale, we swallow in part, too. We swallow our saliva, we swallow part of our nasal secretion, we swallow part of our sputum, and this way we get some of the beta-naphthylamine into our digestive system. It is not a pure inhalation factor.

Mr. MCDONOUGH. In the factory is it in powder form?

Dr. HUEPER. In powder form. It is flaked.

Mr. KLEINFELD. In view of the latest scientific work on the subject of these dyes, do you think it would be a wise or perhaps conservative move to reinvestigate thoroughly all the coal-tar color dyes which are presently in use with a view to possibly minimizing the hazards, if any?

Dr. HUEPER. Well, from an ideal viewpoint one might answer "Yes." From a practical viewpoint, I only can point out that such an undertaking would be quite expensive, would require a lot of laboratory space, trained personnel, and so on. So I think the best we can do

under the present circumstances is to concentrate on those dyes which for theoretical reasons may appear still to be somewhat suspicious.

Mr. KLEINFELD. Doctor, No. 149 in this list contained in exhibit A for identification is listed as azo compounds. That has an asterisk, too, does it not?

Dr. HUEPER. Yes.

Mr. KLEINFELD. Are any of those compounds presently used in foods or cosmetics to your knowledge?

Dr. HUEPER. Well, many of our aniline dyes are azo compounds. For instance, yellow A. B. and yellow O. B. are azo dyes.

Mr. KLEINFELD. Are there any other azo dyes now in use which are suspected?

Dr. HUEPER. Not among the list of the certified dyes.

Mr. KLEINFELD. Some that are not certified are suspected?

Dr. HUEPER. The best known example of that is the so-called butter yellow, which has not been used in American foods and cosmetics since 1919. But I understand it is used for coloring gasoline. That dye will produce in rats and mice, when fed, cancer of the liver and derivatives of this particular compound, dimethyl amino azo benzol, will produce cancer in other organs like the bladder, uterus, and so on.

Mr. KLEINFELD. Do you know, Doctor, that various uncertified coal-tar dyes are permitted under the present law for use in cosmetics if applied on the hair under certain conditions of use?

Dr. HUEPER. I have not studied that.

Mr. KLEINFELD. Doctor, No. 146 on this same list of which we have been speaking is listed as arsenic and its compounds. Is arsenic a recognized cancer-producing agent?

Dr. HUEPER. Yes, sir, arsenicals are known carcinogenic agents.

Mr. KLEINFELD. What kind of cancer do they produce?

Dr. HUEPER. They produce mainly cancer of the skin. Recent experiences suggest that inhalation of arsenicals might produce cancer of the lungs.

Mr. KLEINFELD. Are arsenicals used as pesticides?

Dr. HUEPER. Yes, sir, there are various arsenicals on the market which are used for that purpose.

Mr. KLEINFELD. Can the ingestion of small amounts of arsenic produce cancer, in your opinion?

Dr. HUEPER. Yes, I think that evidence is quite definite.

There are two endemic foci of chronic arsenicism associated with the occurrence of cancer of skin among the exposed population. One is now extinguished. It was the area in Reichenstein where the drinking water supply was contaminated with arsenic from old mine dumps, and there was an endemic focus of skin cancer among the population.

There is still an active focus present in Argentina in the region of Cordova where they have about 100 cases of skin cancer among the population. It is connected with the coexistence of arsenical dermatosis, which is a chronic change preceding the development of cancer.

Mr. KLEINFELD. Doctor, small amounts of arsenic may be found on some foods because of the use of the arsenicals as pesticides in the production of these foods. May this constitute a cancer hazard?

Dr. HUEPER. It may if the arsenic contamination is sufficiently powerful to produce chronic arsenicism.

The evidence comes from Germany again where vineyard workers in the Rhine district had an epidemic of chronic arsenic poisoning

between 1938 and 1942 when the use of arsenicals in vineyards was prohibited by law. During that period they have observed in addition to other signs of chronic arsenicism also appreciable number of skin cancers among vineyard workers. Also the persons who drank wine or the fresh grape juice contaminated with arsenical insecticide residues developed in isolated cases cancer of the skin.

Mr. KLEINFELD. Dr. Hueper, it has been testified before this committee that the Public Health Service conducted tests to determine the safe tolerance of arsenic and its compounds on foods. Are you familiar with that?

Dr. HUEPER. Well, I know only the fact that they have.

Mr. KLEINFELD. Do you know whether these tolerances were established on the basis of the cancer-producing properties of these compounds?

Dr. HUEPER. They have produced—they have issued some regulations on that, but since we do not know the minimal dose of arsenic which may cause cancer, I think that the regulations are based on toxicity and not on carcinogenicity of arsenic.

Mr. KLEINFELD. So that as a general rule, in determining whether a particular substance is toxic either from an acute or chronic viewpoint, it does not necessarily follow that the results will indicate whether the substance is cancer-producing; is that correct?

Dr. HUEPER. No, there is no relation between the toxicity of a chemical and its possible carcinogenic action.

For instance, coming back to beta-naphthylamine, beta-naphthylamine is very little toxic. We scarcely know of any case of beta-naphthylamine poisoning among dye workers, but the substance is highly carcinogenic.

Mr. KLEINFELD. You may have mentioned this, Doctor. If so, I will ask you to repeat it. Do we know the lowest level of arsenic which, if ingested, may produce cancer?

Dr. HUEPER. No, we don't know that. But Neubauer in a very large monograph on arsenic cancer published in 1947 in the British Journal of Cancer analyzed the total evidence that was available in the literature and came up with the following figures: The total amount of arsenic ingested by individuals which developed arsenic cancer of the skin showed a range of 0.19 grams of arsenic to 121 grams. So the range is enormous.

Mr. KLEINFELD. From what we know about cancer, if arsenic may be found on foods, do you think it is important to find out the lowest level which, if ingested, may produce cancer? Should that be determined before a tolerance is set for such a compound?

Dr. HUEPER. Yes, but from a practical viewpoint the important question is not the amount of arsenic per unit of food. The important question is the amount of arsenic consumed by the individual from all sources through the period of a year, let's say, because there are contacts with arsenic from various sources. Arsenic is a substance which is ubiquitary. We find it practically everywhere. We cannot avoid contact with arsenic by any means. The only thing we can do is minimize the contact.

Mr. KLEINFELD. That would be generally true with any substance?

Dr. HUEPER. That is right.

Mr. KLEINFELD. We would have to take the whole picture into consideration?

Dr. HUEPER. That is right. For instance, we know that excessive exposure to sunlight will cause cancer of the exposed skin, but we surely cannot get away from sunlight. We only can take care that we are not excessively exposed to sunlight. That is all we can do.

Mr. KLEINFELD. Could we take care of our exposure to ultraviolet lamps?

Dr. HUEPER. Well, excessive exposure to ultraviolet lamp naturally may also result in cancer of the skin, especially in fair-complexioned individuals, if that particular ultraviolet burner contained the carcinogenic rays. There is a very definite range of ultraviolet rays which is carcinogenic, and some of the burners do not contain that range.

Mr. KLEINFELD. Although we cannot avoid exposure to the sun—and I suppose we would not want to—we can be somewhat circumspect and careful in using ultraviolet rays?

Dr. HUEPER. That is right.

Mr. KLEINFELD. Page 5 of the booklet marked "Exhibit A" for identification, A Methodology for Environmental and Occupational Cancer Surveys, indicates that arsenicals are used in hair lotions and tonics. Do you consider such use a cancer hazard?

Dr. HUEPER. Well, in the sense that it just adds to the others. It may add to our general exposure.

Mr. KLEINFELD. No. 162 on the list to which we have been referring is listed as carbon black. What is the evidence concerning carbon black and its relationship to cancer?

Dr. HUEPER. Well, carbon black is the product of incomplete combustion of various carbonaceous materials such as natural gas, petroleum, oil residues, bone, and other substances. For instance, you have lampblack, bone black, acetylene black, depending upon the materials from which the carbon blacks are produced.

Mr. KLEINFELD. What is the evidence concerning carbon black's relation to cancer? Is there any evidence?

Dr. HUEPER. There are a few cases in the literature of skin cancer among carbon-black workers, but the main evidence is of rather recent date.

Investigators of the University of Chicago—Falk, Steiner, and others—could isolate from carbon black, as it is used in rubber tires to a large degree, several known carcinogenic hydrocarbons. Experiments made with the benzol extract from carbon black in the hands of two investigators produced cancer of the skin in mice.

Mr. KLEINFELD. Page 5 of the same booklet, exhibit A for identification, states that lampblack has been used in eyebrow pencils. Would such use constitute a cancer hazard?

Dr. HUEPER. Well, lampblack is one carbon black which contains a relatively large amount of tar. It is the tar content in carbon black which apparently is responsible for its potential carcinogenic action. There are carbon blacks which scarcely contain any tars—the channel blacks, for instance, scarcely containing any tar, while the furnace blacks do. The lampblack contains quite an appreciable amount of tar, and I would feel that the application of a preparation which contains lampblack over a restricted area containing rather large numbers of sebaceous glands might in the long run become hazardous.

Mr. KLEINFELD. Doctor, we have been advised that carbon black is presently in use in various forms in other cosmetics and in foods. Would you consider that to be some hazard?

Dr. HUEPER. I am not familiar with the evidence, but I have information from Germany that it was recently forbidden to use carbon black for coloring imitation caviar. The imitation caviar, you know, has a reddish color, and to make it look like genuine Russian caviar the manufacturers added carbon black to it. That has been forbidden.

Mr. KLEINFELD. Fairly recently?

Dr. HUEPER. Very recently. I have that information very recently.

Mr. MCDONOUGH. Doctor, is the carbon black which may bring about cancer a stimulant of a latent organic germ in the system that brings it about, or is it the material itself that causes the cancer?

Dr. HUEPER. No, the carbon black, as I said, contains tar, and the tar contains known carcinogenic hydrocarbons that are chemicals of which we know from experience, animal experience, that we can produce cancer with them. Now your question goes a little bit deeper. You want to know whether the carcinogenic chemical does the job by itself or whether the chemical stimulates something in the body?

Mr. MCDONOUGH. That is right.

Dr. HUEPER. That is too deep. We do not know yet.

Mr. MCDONOUGH. You don't know that?

Dr. HUEPER. No.

Mr. MCDONOUGH. Well, here is an individual that has no evidence of cancer.

Dr. HUEPER. Yes.

Mr. MCDONOUGH. And he goes into a factory and works in carbon black or arsenical materials or in beta-napthylamine, and he comes in contact with those things that produce cancer.

Dr. HUEPER. Yes.

Mr. MCDONOUGH. You do not know whether that man had any latent cancer germs in his system before he went to work in that factory?

Dr. HUEPER. Well, I think in most of the industries where known cancer has existed, or where hazards exist, the employer tries to obtain the preemployment history of the man so he does not put a man to work in a hazardous operation who had already a previous significant exposure to another carcinogenic hydrocarbon. For instance, I would say men who would work in a beta-napthylamine operation should be questioned whether they had any previous exposures, because he may just be on the brink or the end of his latent period, and the factory which employs him lastly will get the blame and has to pay the bill for something somebody else has really been responsible for.

Mr. MCDONOUGH. Is cancer a germ?

Dr. HUEPER. I wouldn't think so. Although, let's say, human cancer, I don't think we have any evidence that the fundamental carcinogenic mechanism is an infection, although we have evidence that some cancers in animals are due to a virus infection. For instance, some cancers in birds are known to be due to viruses. But as far as the human cancer is concerned we have no evidence.

Some cancer research workers believe the carcinogenic agents stimulate a silent virus infection and that the silent virus infection in our tissues is the actual carcinogenic cause, cancer-producing cause, but that is still very speculative.

Mr. KLEINFELD. Dr. Hueper, No. 170 on the list to which we have been referring is listed as chlorinated hydrocarbons. Is DDT a chlorinated hydrocarbon?

Dr. HUEPER. Yes, DDT is a chlorinated hydrocarbon.

Mr. KLEINFELD. What are a few of the other chlorinated hydrocarbons?

Dr. HUEPER. Chlordane and benzene hexachloride and there are others.

Mr. KLEINFELD. These are used as insecticides; are they not, Doctor?

Dr. HUEPER. Yes.

Dr. KLEINFELD. What is the evidence, if any, that these chlorinated hydrocarbons may be carcinogenic?

Dr. HUEPER. I think we have to get away from the word "carcinogenic" here. We have to use a more neutral term and say "tumor-producing," leaving it open whether the tumors produced are actually carcinomas or not, or cancers or not.

The members of the Food and Drug Administration, when feeding large amounts of DDT to rats, obtained in a significant number of the rats that were fed tumors of the liver.

Experiments of a member of the National Cancer Institute, I am told, using mice, did not obtain such changes in the liver, although one can produce tumors of the liver with other chlorinated hydrocarbons. Tetrachloride or chloroform will do that job when given to mice.

Mr. KLEINFELD. Do we now know what the lowest level of chlorinated hydrocarbons, if ingested, will cause a tumor, whether benign or cancerous, in human beings?

Dr. HUEPER. I think I should emphasize that we have no record of human cancer from exposure to DDT, although we have evidence of cases of severe liver poisoning from exposure to other more powerful liver toxic agents like chloroform and carbon tetrachloride, but none of those chlorinated hydrocarbons so far, as far as we know, has caused cancer in men.

Mr. KLEINFELD. Are you aware, Dr. Hueper, there has been considerable evidence before this committee that DDT is accumulating in the fat of many people who are not directly exposed to it?

Dr. HUEPER. Yes.

Mr. KLEINFELD. Would such an accumulation of DDT in the fat of the ordinary person, young or old, well or sick, possibly create some hazards?

Dr. HUEPER. I think on the basis of the evidence we have right now we cannot say. We have to wait, perhaps, 10 or 15 years to see whether such evidence may be forthcoming.

Mr. KLEINFELD. You mean you cannot say whether it will or will not constitute a hazard?

Dr. HUEPER. That is right. The possibility probably will depend on the fact whether the accumulation of DDT will be so extensive that finally damage to the liver may result.

Mr. KLEINFELD. Do you know of any concrete evidence that such an accumulation will not produce harm in the future?

Dr. HUEPER. That would be rather speculative.

Mr. KLEINFELD. You don't know, do you?

Dr. HUEPER. I don't know that.

Mr. KLEINFELD. You don't know whether such evidence exists?

Dr. HUEPER. No, I don't know that.

Mr. KLEINFELD. Nos. 187 and 188 in the list to which we have been referring, exhibit A for identification, are listed as synthetic and natural estrogens. What is the evidence on those?

Dr. HUEPER. Your question is highly controversial at the present time, and the positive evidence we have comes mainly from animal experimentation. We know that the administration of estrogens to certain inbred strains of mice will produce in these mice cancer of the breast, of the uterus, of the bladder, as well as leukemia, that is, cancer of the blood-forming organs. And we can get cancer of the breast and of the bladder in certain inbred strains of rats. But that does not hold true to all strains of rats.

There is some suggestive clinical evidence. I must say here I am quoting only the evidence which supports the carcinogenic action, possible carcinogenic action of estrogens.

We know that the state of excessive estrogenism in the body is apparently related to cancer of the body of the uterus. That conclusion has been derived from the frequent coexistence of estrogen-forming tumors of the ovary and cancer of the uterus.

Then we know that gynecomastia, that is hyperplasia or proliferation of the breast tissue in males, precedes in 10 to 15 percent the development of cancer of the breast in males. Gynecomastia will develop in males under the influence of estrogen. We have a very striking illustration of that fact, not only from the therapeutic field where males were treated with large amounts of stilbestrol for cancer of the prostate and have developed enlarged breasts, but pharmaceutical workers engaged in the manufacturing and controlling of stilbestrols have developed swelling of the breasts, often bilateral swellings of the breast.

I know of one case in this country of a chemist who was employed by a house in New Jersey who had both breasts amputated for benign tumors of the breast quite recently.

Then we have the evidence that since 1946, when larger numbers of prostate cancers were treated with considerable amount of stilbestrol, some of these men, if they survive long enough, developed cancer of the breast, one side or both sides. A total of 17 cases is on record from here and abroad. However, the nature of these cancers is somewhat controversial because some investigators maintain that these cancers are not primary but they are really metastases or daughter tumors from the prostrate cancer.

Mr. KLEINFELD. Doctor, is diethylstilbestrol a synthetic estrogen?

Dr. HUEPER. Yes, it is.

Mr. KLEINFELD. Would you say, from your experience, that this class is suspected and that more investigation is needed to be reasonably certain that the addition of the substances in foods or cosmetics will not produce or aid in the production of cancer?

Dr. HUEPER. I feel that rather thorough study should be made on that point, and the studies should be conducted mainly on parts of the human population at the present time having contact with excessive amount of estrogens.

Mr. KLEINFELD. You think there should be further investigation?

Dr. HUEPER. That is right, because only the human evidence finally will be conclusive. We can argue the animal evidence until eternity and that will not give us the final answer.

Mr. KLEINFELD. Can you get any indication or hint right now from the animal evidence so far?

Dr. HUEPER. Well, I mentioned that mice and rats will produce cancer of the breasts and of other organs when given considerable amount of estrogen, both males and females.

Mr. KLEINFELD. Are you familiar, Dr. Hueper, with the current practice of implanting a 15-milligram pellet of diethylstilbestrol in the necks of chickens for the so-called chemical caponizing of the poultry?

Dr. HUEPER. I have read about it.

Mr. KLEINFELD. In view of the apparent suspicions concerning diethylstilbestrol in producing cancer, do you think that is a wise practice at this time?

Dr. HUEPER. Well, the dose of 15 milligrams of diethylstilbestrol compares pretty well with the daily dose that is given to prostate cancer patients which varies anywhere between 1 milligram to about 30 milligrams per day.

Mr. KLEINFELD. Do you draw any conclusion from that?

Dr. HUEPER. Well, I think the practical question that has to be considered is whether the pellet is always implanted just beneath the neck or whether the pellet sometimes find its way into other parts of the body; whether the farmer, for instance, for convenience sake will implant the pellet into the breast tissue, and whether he may not sometimes think if one pellet is good, three pellets are so much better, and then we have the possibility that a person who consumes the breast meat will obtain a rather large amount of estrogen at one shot.

Mr. KLEINFELD. Dr. Hueper, the situation now appears to be this: There are apparently many, many thousands of farmers throughout the country who are implanting diethylstilbestrol pellets in their poultry for the chemical caponizing effect.

In New York, recently, the Food and Drug Administration testified before this committee that seizures of poultry in the New York City area within the last 6 months revealed the presence in the poultry of from one to four pellets, I believe, of the diethylstilbestrol, a good part of it apparently unabsorbed.

The testimony revealed, also, that some of these pellets were not implanted exactly where they were supposed to be implanted, in the base of the skull.

Does that accentuate the problem, in your opinion?

Dr. HUEPER. I think, as I pointed out, it does. I think on general principles it is not wise to hand over to lay persons who can scarcely be fair judges on the biological potency such materials and substances, which may prove to be a sort of biological dynamite.

Mr. KLEINFELD. May it not be an actual human tendency for many people to say, well, if one may do the trick, perhaps two or three will do the trick faster.

Dr. HUEPER. That is not unusual.

Mr. KLEINFELD. And that would increase the problem, would it not?

Dr. HUEPER. It might.

Dr. MILLER. I would like to pursue that just a little further. Of course, we are living in an age where changes take place, and the changes in the scientific advances have been tremendous.

Now, the use of estrogens by the agricultural people, the veterinarians, in sheep, for instance—they feel that probably in the near future they may be able to increase the number of sheep. I think an article appeared just recently which indicated that they can get two lambs a year, and that the ewe will give more milk to the lambs by the use of certain estrogens.

You would not want to say that this scientific advance, this study, should be held in abeyance until——

Dr. HUEPER. Oh, no.

Dr. MILLER (continuing). Until we learn more about it.

Dr. HUEPER. That is an application which has really nothing to do with the consumption of food treated that way.

Dr. MILLER. They use the estrogens on the animals, not only in sheep but in hogs. There have been scientific advances in the use of aureomycin in hogs, to kill bacteria or infections which the hog might have, which would put them on the market earlier than you ordinarily have them go on the market.

Dr. HUEPER. Oh, yes.

Dr. MILLER. All of these scientific discoveries are just another insight in what the human mind and human science can do, given proper scientific studies. Your work has been mostly in the field of cancer. You are in a position to know that sometimes people become impatient because we do not seem to get down to some of the fundamental causes of cancer. I know that we are probably making some progress. I was just wondering whether you had felt since you made the statement about the estrogens in poultry, whether you had the same feeling about their use in sheep or in the agricultural field, where it has been demonstrated that the proper and judicious use of the estrogens can benefit agriculture?

Dr. HUEPER. No, I think there cannot be at the present time any objection against the use of estrogens for that purpose. What my doubts about the advisability of using estrogens in poultry come from is the fact that some of the estrogen may remain in the meat consumed. It has nothing to do with any agricultural practices used for breeding purposes.

Mr. KLEINFELD. Doctor, it has been testified before this committee that there were currently being sold on the market certain estrogenic hormone preparations for cosmetic purposes.

There are creams and oils with a potency of 20,000 international units of estrogen for a 30-day supply per jar.

Apparently cosmetic manufacturers are advertising these products and are encouraging women to apply both oils and creams and lotions on the scalp, the face, the neck, throat, shoulders, arms, hands, elbows, and in some cases the legs.

As many as four or more applications may be made by the same woman every day to different parts of the body, comprising rather large areas of the body, and these will remain on the skin usually for many hours, perhaps 24 hours every day.

In view of the present knowledge on this subject, and looking at it from a possible cancer-producing viewpoint, do you think it is wise for women to use estrogen preparations in such manner?

Dr. HUEPER. Well, from what I know—and I have seen in my professional life—if I were a woman, I do not think I would use estrogenic creams or lotions on my skin.

Mr. KLEINFELD. Why?

Dr. HUEPER. The reason would be that I cannot judge very well whether such applications may not precipitate the development of cancer of the breast or of the uterus.

Mr. KLEINFELD. Might it be an even tougher problem if the woman had a history of cancer in her family?

Dr. HUEPER. Well, I think that would be rather speculative.

Mr. KLEINFELD. In any event, Doctor, if these estrogenic cosmetic preparations are permitted on the public market, do you believe that they should contain a warning of the possible dangers entailed in their use?

Dr. HUEPER. I think on general grounds that might be advisable or desirable.

Mr. KLEINFELD. For example, what kind of warning?

Dr. HUEPER. Well, I would probably mention on the label that the prolonged and excessive use of that particular preparation might entail for predisposed persons a certain amount of health hazard.

Mr. KLEINFELD. From the cancer viewpoint?

Dr. HUEPER. Yes, from that; that is what I would have mainly in mind.

Mr. KLEINFELD. No. 2320 on the list to which we have been referring, exhibit A for identification, is listed and entitled "Paraffin, Paraffin Oil, Crude."

What is the evidence on that?

Dr. HUEPER. We know from European experience and also from very recently published American experience by the staff of the Standard Oil Co. of New Jersey, that workers engaged in the production of paraffin from petroleum oils have an excessive liability to cancer of the skin, mainly cancer of the scrotum. But the carcinogenic agent is not contained in the paraffin proper, in the purified paraffin, but is contained in the oil which is expressed from the crude paraffin.

Mr. KLEINFELD. Do you know, Doctor, that paraffin or similar substances are used extensively as a carrying agent for various insecticides presently in use?

Dr. HUEPER. I am aware that some other petroleum distillates like kerosene or even lighter fractions are used for that purpose. I am not aware that paraffin oils are used for that purpose.

Mr. KLEINFELD. Are you aware of any evidence to show that the vehicles which you have just mentioned have been tested for their possible carcinogenicity?

Dr. HUEPER. I know of one investigation of that type.

Mr. KLEINFELD. What did that disclose?

Dr. HUEPER. The details, the detailed results, are not available to me, but I heard that one of the vehicles tested proved to be carcinogenic to mice, to the skin of mice.

Mr. KLEINFELD. Do you think it would be advisable to test these vehicles for such purpose?

Dr. HUEPER. I think so; that would be a reasonable practice.

Mr. KLEINFELD. Do you have an opinion, Doctor, as to whether various insecticides which are now in use, and which may be present as residues on food, have been adequately tested for their cancer-producing properties?

Dr. HUEPER. I think it is practically impossible to foretell whether or not a certain chemical which has never been used before in the human environment may or may not have a carcinogenic property. So if it is practicable, I think, and not too expensive, one might recommend that.

Mr. KLEINFELD. In other words, if you had the money and facilities, do you think it would be a worth-while task to conduct such an investigation?

Dr. HUEPER. Yes, it would be; but as I wish to point out, any large-scale practice is not only a scientific undertaking but it is an economic undertaking of no small proportions.

Mr. KLEINFELD. Dr. Hueper, are you familiar at all with the history of acetylaminofluorene?

Dr. HUEPER. Yes. Acetylaminofluorene was discovered or was reported in 1941 by English investigators. It was originally developed as an insecticide, but when they determined the chronic toxicity of that compound, they found it was highly carcinogenic. At the present time I think acetylaminofluorene is that chemical carcinogen which can produce cancers in more organs than any other chemical we know of.

Mr. KLEINFELD. Was the discovery that acetylaminofluorene produced cancer an incidental or accidental one, or was an attempt being made to determine that fact?

Dr. HUEPER. The authors make it quite clear in their communication that it was accidental.

Mr. KLEINFELD. When was the discovery made that the substance would produce cancer?

Dr. HUEPER. It was made in 1941, and was published in Cancer Research, in the first volume of that book, that magazine.

Mr. KLEINFELD. In what part or organs of the body did it produce cancer?

Dr. HUEPER. It would produce cancer of the liver, the stomach, the breast, the thyroid, the pelvis of the kidney, the bladder, the female genital tract, the external auditory canal, and occasionally the brain.

Mr. KLEINFELD. After the discovery that this proposed insecticide did produce cancer it was discarded for that use, was it not?

Dr. HUEPER. That is right. It was never used for that purpose.

Mr. KLEINFELD. If the fact that it did produce cancer had not been ascertained in the accidental fashion which you mentioned, it might now be used as an insecticide; is that correct?

Dr. HUEPER. Doubtlessly it would have been.

I may mention that there is another chemical which was similarly discovered, and it is styryl 430, also a very complex aromatic compound which was developed originally as an agent against trypanosomiasis. When it was found out that the chemical was carcinogenic naturally it was not used for that purpose. But we will discover with such routine tests of chronic toxicity only the powerful ones, not the ones that are on the border line.

Mr. KLEINFELD. After the discovery was made with respect to acetylaminofluorene, do you know whether a general program was started by anyone to test other insecticides then in use for their possible tumor-producing or cancer-producing properties?

Dr. HUEPER. Not that I am aware of. There naturally are industrial concerns that have their control operations, so they may do quite a bit of testing which is not published.

Mr. KLEINFELD. Doctor, in checking the publications of which you are an author, we have found one which concerns itself with detergents; is that correct?

Dr. HUEPER. That is right.

Mr. KLEINFELD. By "detergents" do you mean a surface-active agent?

Dr. HUEPER. Yes, a surface-active agent, a wetting agent, an emulsifier, a penetrating agent.

Mr. KLEINFELD. You mean something——

Dr. HUEPER. There are hundreds of compounds of that sort now on the market.

Mr. KLEINFELD. You mean something of the same general class of materials which are used today in foods and cosmetics for their softening and penetrating and emulsifying properties?

Dr. HUEPER. That is right.

Mr. KLEINFELD. These are also called wetting agents, I think you said?

Dr. HUEPER. That is right.

Mr. KLEINFELD. Do you know of any cancer research which has been done with detergents?

Dr. HUEPER. From the published reports I do not feel that there have been tests to any appreciable degree for carcinogenic properties. I do not think anybody has gone into that phase very well.

Mr. KLEINFELD. Do you think anybody should?

Dr. HUEPER. I think so, because quite a number of them are aromatic compounds; they are not all aliphatic compounds.

Mr. KLEINFELD. Some research has been done, has there not?

Dr. HUEPER. But they have been used in experimental work as emulsifiers of carcinogenic hydrocarbons, fed to mice, in attempts to produce cancer of the stomach and cancer of the intestinal system.

They were used for the purpose of enhancing the penetration—first, to increase the dispersion of the carcinogenic hydrocarbon into the vehicle, and incidentally also one would produce an increased permeability of the gastrointestinal mucosa to these hydrocarbons, and that has been shown by Finnish workers very brilliantly with fluorescent light.

Mr. KLEINFELD. I think you said that you believe considerably more research work is needed?

Dr. HUEPER. That is right.

Mr. KLEINFELD. Would you say, Doctor, that these detergents or wetting agents may favor the penetration of various carcinogenic substances into the system, thus increasing the cancer hazard involved?

Dr. HUEPER. Well, let us point out here that you are talking about detergents in general, and not about any specific detergent.

Mr. KLEINFELD. That is correct.

Dr. HUEPER. That is the conclusion which the Finnish workers arrived at, that they could produce cancer of the stomach when they solubilized the carcinogenic hydrocarbons in a watery medium they could produce cancer of the stomach with a very low dose of carcinogen in a very short period of time.

Mr. KLEINFELD. Is it not true, Dr. Hueper, that some types of surface-active agents occur naturally in the food we eat?

Dr. HUEPER. That is right. We have always surface active agents in our food.

Mr. KLEINFELD. Would the addition of other surface active agents, or even greater quantities of those that occur naturally, possibly increase the risks so far as cancer is concerned?

Dr. HUEPER. That would somewhat depend upon the chemical nature of the particular detergents.

Detergents are anionic, cationic, or nonionic. If one mixes anionic and cationic, that might destroy their action. So one would only say that if the detergents are of a compatible type there may result an accentuation of their action.

Mr. KLEINFELD. I gather from your testimony, Dr. Hueper, that even natural substances, even natural surface active agents normally in the body, may possibly be a factor in the production of cancer. Is that a fair statement?

Dr. HUEPER. Would you repeat that question?

Mr. KLEINFELD. I believe I gathered from your testimony that even substances naturally in the body, surface active agents particularly, naturally in the body, might possibly be a causative factor in the production of cancer.

Dr. HUEPER. I do not think I would like to commit myself on that.

Mr. MCDONOUGH. Pardon me. In other words, is it not possible to develop cancer except by some outside contact? The question he asked is, Is there anything in the human system that brings about cancer without contact from something on the outside.

Dr. HUEPER. Well, we talk about the so-called endogenous carcinogens, which are agents that are produced in the human body or in the animal body.

I would consider that as quite possible. The hormones, the estrogens, for instance, would go into that category.

Mr. MCDONOUGH. You mean the natural estrogens, not the chemical or synthetic?

Dr. HUEPER. That is right; or abnormal products of the steroid group might go into that line which are produced by disturbing the hormonal metabolism. But you see, we are not sure about that, but there is suggestive evidence which would support such a finding. It is by no means—I would not like to leave the impression that everything is environmental.

Mr. KLEINFELD. Looking at it from another angle, Doctor, the fact that a substance may occur naturally in a food which we may eat, does that mean that it is perfectly safe?

Dr. HUEPER. The natural detergents?

Mr. KLEINFELD. Yes.

Dr. HUEPER. Well, I think living is a little bit risky, as it is. [Laughter.]

I do not think we can make living a hundred percent safe.

Mr. KLEINFELD. That is right. That is the point I am trying to make, Doctor. There are some things we just cannot avoid. For example, you mentioned sunlight.

Dr. HUEPER. That is right.

Mr. KLEINFELD. Of course, we have to live, and we have to eat foods, but there may be some substances in natural foods that you may be suspicious of, is that correct?

Dr. HUEPER. There may probably be very distinct individual differences, too, of a constitutional factor that will enter into that picture.

Mr. KLEINFELD. As you say, we have to keep on living as best we can, and thus eat foods with various things which are naturally within the foods. Does that mean we have to be less careful of the things we add to our food supply and cosmetic supply?

Dr. HUEPER. No. I think we should be conscious of our environment. Perhaps we have not been conscious enough. If we look over

our more recent medical literature we have become conscious of a new type of medicine which is called environmental medicine. That is something new. The environment has always been with us, it only changes somewhat, and the factors in our environment which may cause disease change as we develop industries and our agriculture and whatever we do, so, there are very definite limiting factors to that.

Mr. KLEINFELD. If we want to add various surface active agents to our food supply, do you think they should be carefully studied from the possible cancer-producing viewpoint?

Dr. HUEPER. If that is practicable, I would advise that.

Mr. KLEINFELD. Is there any relationship, Dr. Hueper, between the duration and intensity of exposure to a carcinogen and the production of cancer?

Dr. HUEPER. Yes, there is a very definite relationship.

The higher the dose or the more intense the exposure and the longer the exposure the quicker will be the development of cancer, in a general way.

Mr. KLEINFELD. Must there be a continuous exposure in order to get cancer?

Dr. HUEPER. No, that is not necessary. For instance, many of the occupational cancers are due to intermittent exposures.

Mr. KLEINFELD. Must there necessarily be a large degree of exposure?

Dr. HUEPER. That entirely depends upon the type of carcinogen. For instance, exposure to beta-naphthylamine to produce cancer of the bladder may apparently be very minute.

The medical director of the du Pont Co., Dr. Gehrmann, in one of his papers states that workers employed in an old plant formerly used for the production of beta-naphythylamine, may run a bladder cancer hazard. So the exposure under such conditions must be very minute.

We have some experimental evidence about the smallest amount of carcinogen which may produce a cancer in a mouse. It is 0.4 microgram or four-tenths of a thousandth of a milligram, but there are still many billions of molecules in that dose, so we are still pretty far from producing a cancer with one molecule of carcinogen.

Mr. MCDONOUGH. You say the minimum dose is 0.4 gamma?

Dr. HUEPER. With which we have been able to produce a cancer.

Mr. MCDONOUGH. You have been able to produce with that?

Dr. HUEPER. Dr. Shear from the National Cancer Institute——

Mr. MCDONOUGH. You say by——

Dr. HUEPER. By injection in the mouse.

Mr. MCDONOUGH. In a mouse?

Dr. HUEPER. In a mouse; yes. Where we stand with a human being we do not know at all. We have no definite information at all.

Mr. MCDONOUGH. Would you say that the amount that would cause cancer in a human being would be greater than that? Of course, the mouse is not as——

Dr. HUEPER. No.

Mr. MCDONOUGH. (continuing). Resistant as the human being would be, is he?

Dr. HUEPER. No, you cannot argue quite that way. If the material stays in one spot and has concentrated action it may be very small. It may not be very large at all, the amount.

You see, if you distributed the small amount over the entire body you get a much larger spread, but if the material action is from one single focus, you may need only a very small amount.

Mr. McDonough. Then it spreads through the system?

Dr. Hueper. Well, it may?

Mr. McDonough. It may?

Dr. Hueper. It may and it may not. It depends on the solubility of the material.

Dr. Miller. Mr. Counsel, I will have to leave shortly, and I want to ask the doctor some questions.

The doctor is an expert on cancer, and he may confound and confuse some of the minds upon this side of the table. But to be practical about it, do you have any thoughts or any ideas about legislation that might be needed to correct any of the problems that you raised here this morning?

Dr. Hueper. It may be advisable to have laws which require that all new chemical additives to foods are previously tested for toxic and possibly carcinogenic properties.

Dr. Miller. Would you include cosmetics in that?

Dr. Hueper. Oh, I sure would.

Dr. Miller. The committee, of course, will be interested in that phase in its report.

Of course, a human being, being so complex as it is, what might be one person's food might be another one's poison——

Dr. Hueper. That is quite right.

Dr. Miller (continuing). As we have heard; and I think probably it is true that we react differently. There are so many things that we do not know, that I sometimes think perhaps the human race would be happier if we could accept the theory of acceptability, accept things as they are, and do the best we can with them. If we can grow old gracefully and contented in mind and spirit, why, maybe we have completed the cycle and function of life.

However, here we are dealing with a complex and intricate subject of chemicals. The reaction you might get in one person might be different in someone else.

I am wondering just how long it is going to take to reach definite conclusions as to whether this detergent or this chemical should or should not be used in food.

It sometimes seems to lay people that the scientific people proceed rather slowly as to why there is cancer, what causes it, and how to diagnose and stop it. That would be applied to polio and other diseases.

The question I wanted to ask was whether you would want to hold up the complete use of many of these chemicals, ban them entirely, until science may or may not have found an answer as to whether they are good or bad for the human being?

Dr. Hueper. If you would apply that strictly, I think at the present status of our knowledge you might have to close down quite a bit of our industrial establishments.

Dr. Miller. That is quite right.

Dr. Hueper. I do not think you can do that here.

Dr. Miller. In other words, we learn about many of these things by trial and error—we reach the conclusion through trial and error.

Dr. Hueper. That is right. You have to do some selection. You

have to run certain things on a priority basis because they are either mainly used; they are really——

Dr. MILLER. That is right.

Dr. HUEPER (continuing). Products which constitute a general hazard to which larger portions of the population are exposed, or there is some indication from theoretical grounds or practical grounds from other fields that a certain material may be hazardous. I think that is the only thing one can do right now. But I think that that somewhat discouraging fact should not hold us back from doing something, and not do anything. We should not do nothing.

Dr. MILLER. Yes, I favor that because I am sure that neither you nor our counsel wanted to leave the impression that sunlight was not good for some of us, because Florida and California might object having that in the record. [Laughter.]

I think the judicious use, perhaps——

Dr. HUEPER. Yes, that is right.

Dr. MILLER. That is the word you should use, and which should be beneficial, and the judicious use of food, perhaps, is good for the human being.

Some of us dig our graves with our teeth——

Dr. HUEPER. That is right.

Dr. MILLER (continuing). By eating too much and eating improper food. But the thing I wanted to ask you is what suggestions you might give to the committee on this use of estrogens? What recommendations on the use in toilet preparations, cold creams, etc.? What recommendations on the use of chemicals in food? I would appreciate your viewpoint.

Dr. HUEPER. I would feel that the uncontrolled use of any known or suspected agent with carcinogenic properties is not advisable, and that certain control measures should be taken.

For instance, you mentioned estrogens. I do not feel that one can give to the average farmer estrogen preparations without exerting some control so that they are actually implanted where they should be.

Mr. MCDONOUGH. What about estrogenic hormones? We had evidence before the committee previously that the application of estrogenic hormones to the surface of the skin was more dangerous than taking it through the alimentary canal, that it was more quickly absorbed.

Dr. HUEPER. Especially, for instance, if you use an ointment which contains a detergent, you can bring estrogen very quickly through the human skin.

Mr. MCDONOUGH. You mean that in the use of estrogenic hormones, in the application of stilbestrol or in cosmetics through oil or creams, they should be under more control than they are at the present time in protecting public health?

Dr. HUEPER. From my personal viewpoint, yes.

Mr. MCDONOUGH. From your personal viewpoint?

Dr. HUEPER. Yes.

Mr. MCDONOUGH. Do you see that in a practical way insofar as legislation is concerned?

Dr. HUEPER. Well, if you put a warning on the label, I think you will have a really good effect.

Dr. MILLER. Would you do that with softeners used in bread?

Dr. HUEPER. If you can show, if you can demonstrate, that the material is hazardous to health.

Dr. MILLER. If you can show that?

Dr. HUEPER. That is right. Naturally, you would have to show that. Nobody can pass regulations without a factual basis.

Dr. MILLER. That is a pretty big "if," is it not?

Dr. HUEPER. That is right. One has to base any law on some evidence.

Mr. MCDONOUGH. Of course, in the environment, in an industry where the workman is exposed, that is the responsibility both of himself and the plant management; that is not of general application to the public.

Dr. HUEPER. That is right.

Mr. MCDONOUGH. And there should be precautions used there insofar as safety to the health of the individual is concerned. But where they are delivered to the public over the counter, sold and bought promiscuously, you think the only precaution necessary is a precaution on the label?

Dr. HUEPER. For some materials that might be sufficient. But for materials for which we have very definite evidence that they are hazardous in the amounts present in the food, no; I probably would use very much stronger measures. It depends entirely on the type of evidence that is available for a particular compound.

The CHAIRMAN. Go ahead.

Mr. KLEINFELD. Are you generally familiar, Doctor, with the new drug section of the Food and Drug Act?

Dr. HUEPER. In a very general way; yes.

Mr. KLEINFELD. You know that provides generally that before a new drug, as defined in the statute, may be placed on the market, evidence as to its safety must first be presented to the Food and Drug Administration? Do you know whether that has, as far as you know, hindered progress and research in the drug field?

Dr. HUEPER. Not from my observations in the pharmaceutical industry.

Mr. KLEINFELD. Again under that section as applied to new drugs, a manufacturer has the burden of proof of establishing that the product, the new drug he wants to put on the market, is safe. He must prove that.

Is there any reason why a manufacturer who is putting out a chemical for use in a food should not have the same burden of proof imposed upon him?

Dr. HUEPER. Probably the population is exposed to materials in food more than any other product. Certainly they are exposed more than they are to cosmetics or medicines; and from that viewpoint alone I think it would be advisable that chemical additives to foods, especially any one which might be introduced in the future, be tested for toxic properties, especially toxic properties which might become manifest in the very prolonged exposure in relatively small doses as they may exist in the food.

Mr. KLEINFELD. Is it not a fact, Doctor, that a cancer may develop even though no toxic symptoms may display themselves for considerable periods of time?

Dr. HUEPER. That is correct.

Mr. KLEINFELD. So that cancer may develop many years after exposure to a particular substance has ceased; is that correct?

Dr. HUEPER. That is correct.

Mr. KLEINFELD. Do related chemical compounds necessarily have the same effect, as far as cancer production is concerned?

Dr. HUEPER. No; there is a very great specificity in the carcinogenic action of related compounds, as I pointed out already before.

Mr. KLEINFELD. This may be repetitious, but is it a fact that you can be in contact with a carcinogenic agent for a long period of time and not feel any ill effects, or show any toxic symptoms, although the agent eventually does produce a cancer?

Dr. HUEPER. That is correct; such examples exist.

Mr. KLEINFELD. Doctor, in testing with respect to carcinogenicity, is it sufficient that a particular chemical used in a food or cosmetic be tested by itself, or should it be tested in conjunction with the other components of the product, and possibly other products customarily used by people?

Dr. HUEPER. It should be tested both ways. If a chemical goes into food material, it should be tested alone as well as in conjunction with the vehicles in which it is ingested.

Mr. KLEINFELD. Why is that, Doctor?

Dr. HUEPER. The vehicle as such may act either as an inhibiting agent or as a favoring agent.

Mr. KLEINFELD. What kind of tests do you believe should be performed?

Dr. HUEPER. The material should be introduced through various routes, and various species should be used in testing the material.

Moreover, it would be advisable to observe also the offspring so as to obviate any transplacental action of such a material.

Mr. KLEINFELD. Are you saying there should be several species of animals and more than one generation?

Dr. HUEPER. That is right.

The CHAIRMAN. Doctor, in behalf of the committee, and personally, I want to express to you our thanks for your time and effort in coming here and attempting to help us out on these complex problems that we have.

I am sorry that more of the members of the committee were not here. Two of them are ill, and one has other committee work, but I am sure they will get the benefit of your testimony by reading it in the record.

We are indebted to you.

Dr. HUEPER. Thank you.

The CHAIRMAN. We are indeed indebted to you for a comprehensive report.

Mr. KLEINFELD. Mr. Chairman, just one more thing. I have a letter here dated January 2, 1952, received from the Surgeon General of the Public Health Service, which furnishes reports on data acquired by the Public Health Service laboratory in Wenatchee, Wash., and the Communicable Disease Center at Savannah, Ga., on the presence of pesticides, particularly DDT, in human fat samples and on the pesticidal residues on food products. I suggest that this be placed in the record. It is about a three-page report.

The CHAIRMAN. So ordered.

(The document referred to follows:)

FEDERAL SECURITY AGENCY,
PUBLIC HEALTH SERVICE,
Washington, D. C. January 2, 1952.

Hon. JAMES J. DELANEY,
House of Representatives, Washington, D. C.

DEAR MR. DELANEY: This is in further reply to your request of December 3, 1951, for reports on data acquired by our laboratory in Wenatchee, Wash., and by our Communicable Disease Center at Savannah, Ga., on the presence of any pesticides in human fat samples and on the pesticidal residues on food products.

Enclosed is a brief report which summarizes all of the data obtained by these laboratories up to the present time. As you know, the investigative work is still under way and additional information will become available in the future. Meantime, if there is any additional assistance which we may give you in connection with your investigations, please do not hesitate to call upon us.

Sincerely yours,

LEONARD A. SCHEELE,
Surgeon General.

Enclosure.

SUMMARY OF INVESTIGATIONS ON DDT RESIDUES ON FOODS AND DDT STORAGE IN HUMAN FAT—TECHNICAL DEVELOPMENT BRANCH, COMMUNICABLE DISEASE CENTER, PUBLIC HEALTH SERVICE, SAVANNAH, GA.

The increasing use in recent years of insecticides on crops which are to be used as food has caused concern as to the possible hazard of these insecticide residues. One of the most important compounds in this respect is DDT, both because of its very wide use and its resistance to breakdown by weathering. The Communicable Disease Center of the Public Health Service has approached the study of this problem from two angles: (1) Determination of the amount of DDT residue found on representative samples of fruits at harvest, and (2) analysis for DDT content of human fat taken from volunteers reporting wide ranges of exposure.

Tree fruits were chosen as the subject of the residue study, since they ordinarily receive a considerable amount of insecticides during their growth, and are consumed, usually, without processing.

A total of 98 determinations for DDT residue were run on various samples of washed apples collected in north central Washington. The average DDT content was found to be 1.8 parts per million. A series of 13 analyses carried out on pears showed an average DDT residue of 0.9 parts per million. It may be seen that the DDT residue of the pears tested is considerably less than that of the apples. Some variation was also found in the DDT residue of different varieties of apples. It is possible that this difference can be explained by the DDT-retentive oil and wax content of the cuticles.

An attempt was made to find a correlation between the DDT residue on apples and pears and the spray practices used in their production. When DDT in water suspension was applied by ground equipment, the average residue on the fruit at harvest was found to be in direct ratio to the amount of DDT applied. The residue appeared to be less when DDT was applied as a dust than when an equal amount was applied as a water suspension.

In addition to the study of the actual residue present on food, a study of the degree of exposure of the population to DDT is desirable. This was done by obtaining fat samples from human volunteers, and determining the DDT-content of the sample. An effort was made to obtain these samples from persons representing a wide range of DDT exposure. Specimens were solicited from persons having no known contact with DDT as well as from those having extensive occupational exposure.

As of this date, a total of 113 human fat samples have been analyzed for DDT content. The mean value of the DDT content of 111 of these samples taken from persons with moderate or no known exposure is 6.41 parts per million (p. p. m.). The highest DDT content observed in two workers with extensive exposure was 91 and 291 parts per million.

A breakdown of these samples from a geographical point of view is of some interest. Part of the specimens were taken at Savannah, Ga., which is situated in a nonagricultural area where the exposure of the populace should be minimal; the remainder were taken at Wenatchee, Wash., which is in the heart of an

agricultural section where the use of insecticides is intensive. Thus, a comparison of the DDT content in fat from these two areas should give some insight into the comparative exposure of the populace of the two regions. The mean value of the DDT content from 47 fat samples taken at Wenatchee, Wash., was 5.74±1.03 p. p. m.[1] The value for the 52 specimens collected at Savannah, Ga., was 6.62 p. p. m.±1.75. Thus, it appears that there is no significant difference between the DDT content of human fat samples taken in these two areas. The value for 12 other specimens taken in widely separately areas in Georgia, Virginia, and California was 9.17±3.87. Again no significant difference is apparent.

A breakdown of the reported cases on the basis of degree of exposure was also made. As mentioned above, 2 out of 113 patients were outstanding because of their extensive exposure. Both were employed to work directly with DDT 40 hours a week for 6 to 9 months per year. One man who worked chiefly with 5-percent emulsion showed a DDT value of 91 parts per million. A second test made approximately 2 years after he discontinued exposure showed a value of 30 parts per million. The second patient who was exposed to 25 and 35 percent solutions of DDT showed a value of 291 parts per million. Later, when tested after a winter rest period he showed a value of 240 parts per million. Both men were hospitalized for careful examinations on two occasions and no illness attributable to DDT could be found.

Among the 111 cases taken from the general population an extreme range of 0 to 68 parts per million was found. Eleven cases showed values from 20 to 68 parts per million and of these cases 4 gave a history of no known exposure to DDT. The others had, at most, only moderate exposure. The wide range of values found for the general population has been reported by other laboratories but cannot be explained at this time.

The CHAIRMAN. Is there anything else?

Mr. KLEINFELD. No.

(Whereupon, at 12:05 p. m., the committee adjourned, to reconvene at the call of the Chair.)

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[1] Standard error of the mean.

CHEMICALS IN FOODS AND COSMETICS

THURSDAY, JANUARY 31, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74, and H. Res. 447, 82d Cong., 1st sess., continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 10 a. m., in room 445, Old House Office Building, Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney of New York, Jones of Missouri, Miller of Nebraska, Horan of Washington, and McDonough of California.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will come to order.

Call the first witness, Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Cox.

The CHAIRMAN. Your name and address, Dr. Cox?

Dr. Cox. L. G. Cox, Canajoharie, N. Y.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF L. G. COX, PH. D., BEECH-NUT PACKING CO., CANAJOHARIE, N. Y.

Mr. KLEINFELD. What is your academic background, Dr. Cox?

Dr. Cox. I did my undergraduate work at the Unievrsity of California. I did a year and a half of graduate work there, and I came to Cornell University and obtained my Ph. D. degree in plant physiology, with minors in organic chemistry and soil science.

Mr. KLEINFELD. When did you obtain your Ph. D.?

Dr. Cox. 1942.

Mr. KLEINFELD. What did you do subsequent to 1942?

Dr. Cox. Subsequent to 1942 I was teaching assistant in forestry ecology, University of California, for 2 years; also taught forest survey and forest mensuration for two terms at the University of California summer camp. At Cornell I was research assistant in forest physiology from 1938 to 1941 and from 1941 to 1942 I was an instructor in teaching the physiology of plant propagation.

Mr. KLEINFELD. How long have you been with the Beech-Nut Packing Co.?

Dr. Cox. Five and one-half years.

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Mr. KLEINFELD. Generally speaking, what are your duties?

Dr. COX. I am in charge of special technical projects, which involves practically all of our outside research projects and cuts across more phases of our food business. I have been in and out of practically every research project within our business in some technical capacity.

Mr. KLEINFELD. Will you please read your statement, Doctor.

Dr. COX. My name is L. G. Cox. I am in charge of special technical projects for the Beech-Nut Packing Co., which manufactures baby foods, peanut butter, coffee, and chewing gum.

Prior to the commercial introduction of DDT as an agricultural insecticide, our quality control program consisted of close bacteriological supervision of equipment, raw materials, and finished products; routine insect fragment and mold counts and chemical analyses for lead, arsenic, fluorine, and occasionally copper. Periodic checks were made on agricultural raw materials as they arrived at the plant, again at the end of the customary preparation procedures of washing and peeling, and finally on the finished product, in accordance with well established methods of analysis acceptable both to the National Canners Association and the Food and Drug Administration. In general a simple wash was sufficient to remove most residues, but on some fruits an acid wash was occasionally required to remove excessive residues of lead and arsenic.

The advent of DDT gave us higher quality fruits and vegetables than we had been able to obtain heretofore. But, it also presented a new residue problem with respect to methods of analysis adapted to the minute residues existing on or in food products, methods of economical residue removal, and tolerance standards for residues in the finished product.

Our management immediately made the decision to employ competent chemists in order to develop suitable methods of residue analysis and removal, and gave others of us the responsibility of becoming intimately acquainted with those developments in new pesticides pertinent to our business. This has led to the development of a considerable research program within our own laboratories, supplemented by grants-in-aid to universities, experiment stations, research institutes, and even the Bureau of Plant Industry of the United States Department of Agriculture. Our research staff worked closely with the American Medical Association, the Food and Drug Administration, the United States Department of Agriculture, the American Chemical Society, the National Research Council, the National Canners Association, various insecticide manufacturers, trade associations, and farm organizations. Eventually we were associated with the formation of the pesticide committee of the American Medical Association, the pesticide subdivision of the American Chemical Society, and the food-protection committee of the National Research Council.

WHY BEECH-NUT DEVELOPED A POLICY OF MINIMUM PESTICIDAL RESIDUES IN FOODS

Why did we as early as 1947 deem it necessary to undertake such an extensive and extremely expensive research program on pesticidal residues? Our immediate obligation was to protect the consumer of our products. To do this we immediately had to develop methods of

residue analysis in order to determine whether or not we were providing that protection. Our second obligation was to our stockholders to develop efficient methods of residue removal and an agricultural procurement program which would allow us to operate at a profit. We couldn't take the attitude that all insecticides were harmful, because we needed the production of quality fruits and vegetables at a reasonable price. To achieve this we had to determine which pesticides were effective in use, yet safe for our purposes.

How did we proceed in formulating a procurement procedure and policy which gave us raw materials with minimum residues, and how did we arrive at what we concluded to be a safe residue tolerance in the finished product? First of all we had to obtain facts, either from the published literature or from our own research efforts. Let me quickly summarize our basic reasons for arriving at our present operational policies pertaining to DDT and related insecticides.

1. Toxicological and related data: The insecticide DDT as well as closely related chlorinated hydrocarbons has certain properties which, in the absence of good information to the contrary, have forced us to adopt a near zero tolerance level in baby foods. From the published literature and research programs which were in progress, the results of which have since been published, we have accumulated certain basic information which led us to this policy. This information may be summarized as follows:

(*a*) A relatively high order of chronic toxicity to which there may be individual variations in susceptibility.

Primary consideration was given to the evidence that young animals are usually more susceptible than older ones and occasionally exhibit marked changes in certain organs, even though body growth may be normal, when subjected to the chronic toxic effects of DDT and related chlorinated hydrocarbons.

Fitzhugh (8) noted the storage of DDT in rats along with histopathological effects on diets as low as 10 parts per million, and that 50 parts per million diets reduced the number of weanling rats. Later Lehman (15) reported that rats can begin storing DDT at dietary levels below 1 part per million, and accumulate it in body fat in concentrations of 6 to 28 times that of the original level in the diet. A continued intake of 5 parts per million produces definite but minimal liver damage, and the rate of disappearance of DDT from body tissue is slow.

Radeleff and Bushland (18) (18a), following a series of deaths to young farm animals from commercial treatment by recommended sprays and dips for control of cattle ticks, inaugurated experiments which demonstrated that suckling calves are more susceptible to benzene hexachloride, chlordane, and toxaphene than older animals. More recently during the current hearings, Dr. Harris of the Utah Agricultural Experiment Station (12) has said that young turkey poults exhibit a mortality of 31.5 percent when fed alfalfa hay containing DDT levels of 100 parts per million.

With regard to other changes occurring in certain organs at levels of DDT intake at which body growth was apparently normal, Burlington and Lindeman (3) treated white leghorn cockerels, beginning 8 days after hatching with levels of DDT at which body growth was normal, and found that development of the testicles, comb, and wattles was greatly inhibited. They suggest that DDT may exert an es-

trogen-like action similar to certain sex hormones. Likewise, Emmel and Krupe in Germany (7) had previously found that DDT accumulated in lipid rich organs such as the testicles, thyroid, and adrenals.

With respect to laying hens, Rubin, Bird, Green, and Carter (21) found that levels of DDT feeding at approximately one-half the lethal dose resulted in reduced egg production and hatchability of the eggs. Along the same line, Tauber and Hughes (22), noted that a diet of 100 parts per million of DDT significantly reduced the cholesterol content of the ovaries of female rats, and suggested that cholesterol may be a precursor of progesterone, one of the sex hormones.

The American Medical Association has recently reviewed the pharmacologic and toxicologic aspects of DDT (2) and states that—

> Chronic DDT poisoning may result from the ingestion of small amounts of the material over a long time. Since the chemical is irregularly absorbed, the level, below which adverse long-range effects are absent, is unknown.

They also give emphasis to the Food and Drug Administration having suggested a tolerance of five parts per million as the upper limit on any single item containing DDT residues for human consumption, and less than one part per million if all food is contaminated.

(*b*) DDT tends to be stored at low levels of dietary intake. There is a tendency for it to accumulate in body fat and certain organs at a higher level than the dietary level, and the subsequent rate of disappearance of DDT from body tissues may be slow.

Since we are manufacturers of baby food, we have had to take into account all those factors—prenatal, environmental, physiological, and structural—which may cause a baby to react to food residues in a manner different from the adult.

With regard to prenatal factors, Kinnegan, Haag, and Larson (13) reported that both DDT and DDD are stored in the fatty tissues of dogs, and both are transported across the placental barrier to the fetus. More information of this type is badly needed, particularly in humans. With respect to humans we have indirect data that is of interest, from Lehman (15), and Laug, Kunze, and Prickett (14), which indicates that mother's milk in certain areas may already be averaging 0.14 parts per million DDT, and human body fat may be averaging 5.1 parts per million DDT. The fragmentary data which we have been able to assemble to date indicates, at least, that the newborn baby may already have a slight amount of DDT stored in its tissues, and be receiving additional amounts via its mother's milk prior to the time it is ready for commercial milk or baby food. We are, therefore, of the opinion, that any insecticide residue which tends to accumulate in fatty tissue, should be eliminated insofar as possible from the baby's diet at the time when milk and prepared baby foods are the major part of its diet.

And when I say we are of that opinion, that is as far as our own business is concerned, and the way we operate.

Young animals certainly possess the ability to accumulate DDT in body fat and other tissues in a manner comparable to older animals. We have occasion to believe that in some cases they may tend to accumulate it to a greater degree. Certainly, in the case of infants where there is a relatively high proportion of body fat as compared with adults, we can take few chances with accumulated residues of DDT, or other similar substances, suddenly being released by one of many

infant disorders, which may cause sudden and appreciable loss of body weight through rapid fat metabolism.

Fortunately, we have learned to live with DDT on fruits, at least, through the development of adequate washing or peeling procedures. On potatoes and root crops it presents no problem. On leafy vegetables we do have to avoid the presence of residues at time of harvest, because we have no completely satisfactory method of washing, which leaves the vegetable in a condition for further processing. We have also had difficulty with apricots, which when fully ripe, as we process them, cannot be peeled or given a hot detergent wash. Fortunately parathion and other insecticides, whose residues are completely decomposed by harvesttime, can be used on this fruit with safety.

2. The lack of adequate analytical methods of residue analysis: At the present time we have good analytical methods for DDT, DDD, parathion, benzene hexachloride, methoxychlor and a few other insecticides which are not in general use. Unfortunately, we lack satisfactory analytical methods for chlordane, toxaphene, aldrin, dieldrin, and heptachlor, all of which are either in general use, or show promise of being used on certain crops for which they are badly needed, and if we want to get the quality of food we desire we are going to have to continue to look for good insecticides for which we have a safe story.

Due to our lack of analytical methods, we were obliged to establish an elaborate field survey program through our agricultural purchasing department, and enforce it by a growers contract which prohibits the use of certain questionable pesticides. Some time ago, we received field samples of cabbage, which yielded considerable amounts of an unknown residue in one stage of our DDT analysis. A combination of total chlorine analysis, spot tests, and infrared absorption spectra revealed that it was toxaphene at a level of around 200 parts per million. And to this day we do not know how that farmer was able to get that much toxaphene in his cabbage.

Because of the toxaphene, and other experience, we were forced very early to inaugurate a long-term bio-assay project at the Boyce Thompson Institute for Plant Research. The early phases of this program were devoted to the effect of our methods of processing on the breakdown of known amounts of those insecticides which were either being used commercially, or which showed promise of being used within the near future. As a result of these studies, we knew that parathion, BHC, methoxychlor and a few other insecticides, at levels which normally occurred under good agricultural practice, were largely broken down by processing. DDT and a few others were quite stable, however. In general, the results of this early rough survey were confirmed by subsequent chemical analyses, but we had already been able to establish our basic purchasing policies. On parathion alone, we were able to save many thousands of dollars on apricots, at a time when other more stable insecticides were being highly recommended and widely used.

Recently, we have begun to realize that we may be faced with several years of commercial use of certain insecticides, without any hope of developing a chemical method suitable for residue detection on fresh produce, or in the finished product. Toxaphene and chlordane both fall into this category. We have, therefore, in cooperation

with the National Canners Association, continued a project at the Boyce Thompson Institute with the aim of developing a simple bioassay method, which will be suitable for detecting unknown toxic residues, and expressing them in terms of DDT units. We have already found, however, that the limiting factor is a simple and quick method of separating the pesticidal residue from plant fats, waxes, and interferring substances in such a way that it can be analyzed by bioassay. Certain of the miticides apparently cannot be determined by this type of bioassay. Already this research has paid dividends, for we have found that chlordane, as a soil residue, contaminates carrots. Thus, we have been able to avoid the purchase of carrots from areas where chlordane has been used commercially. Note that Lehman (15) says that—

> It is our opinion that chlordane has no place in the food industry wherever the remotest opportunity for contamination exists.

We are in the peanut-butter business and, as I will explain later, have encountered considerable difficulty in obtaining peanuts free from BHC contamination. Peanuts are grown in rotation with cotton on which large amounts of BHC are used for insect control. Aldrin and dieldrin, and perhaps one other insecticide, show promise on both cotton and peanuts. In order to avoid soil contamination from BHC, we are very anxious to see other good cotton and peanut insecticides developed. We already have samples of peanuts from experiments which have exhibited good insect control, but as yet are unable to analyze these nuts satisfactorily, either chemically or biologically, due to interference from excess peanut oil. If we knew that the insecticides used did not constitute a definite hazard, we would do everything possible to encourage their use as a replacement for BHC in the areas where we normally purchase peanuts.

Because of the lack of adequate methods of residue analysis, we are obliged to maintain a policy of refusing to purchase any crops on which insecticides of high chronic toxicity or off flaver inducing properties have been used, or which come from soils which have been contaminated by these insecticides. This is a policy which involves a hardship on both ourselves and the farmer, and certainly does not make for good farmer-canner relationships, but it has to be done not in our interest, or that of the farmer, but in that of the ultimate consumer, the baby.

3. Off-flavors: (a) Benzene hexachloride: Our first experience, with the actual presence of BHC in or on produce, came during the 1948 season when we had to reject 13 out of 89 acres contracted for squash in Florida, peaches from Pennsylvania, and celery also from Florida. We have done considerable testing of spinach from Pennsylvania and have, over the past 4 years, been forced to reject loads from time to time.

The year 1950 brought to us probably one of the most severe dollars-and-cents losses in handling vegetables exposed to BHC treatment. We were originally contracted in South Carolina for our total requirements of sweetpotatoes. By the time we had tested all of the soils of these contracted acreages, and had found residues of BHC on a large percentage, we were forced into buying on the open market, in South Carolina, North Carolina, and the Eastern Shore of Maryland at much higher prices. The total financial loss amounted to over $15,000.

Our most recent encounter, as far as rejection of fruits is concerned, dates during the 1951 apple season, when we were forced to reject contracted apples in New York because of BHC contamination.

At our California plant we had to reject dehydrated celery in 1949, because of off odor due to BHC contamination. Later in1951 we had to reject carrots, because of BHC soil contamination and residues of BHC in the carrots. The same has been true of California sweetpotatoes, even on fields where the last official record of BHC use was 2 years ago. All other sweetpotato growers contacted admitted the use of Lindane or BHC, and we had considerable difficulty in obtaining satisfactory lots of sweetpotatoes free of BHC for our processing purposes.

Our worst experience, with mass contamination of an agricultural crop, has been with peanuts from the Southeast, where they are customarily grown in rotation with cotton on which BHC has been used for the control of certain insects. Recently Poos, Dobbins, Batten, and Boush of the USDA have reported off flavors in peanuts and peanut cooking oils from plots treated with various levels of Lindane and technical BHC (17). Their data show that peanuts are capable of accumulating considerable amounts of BHC from soils, where it had been added either with or without fertilizer. At rates of application of BHC or Lindane at 1 to 1.25 pound per acre, the corresponding values in the nuts ranged from two to eight parts per million. Panel tests at Beltsville, Cornell University, peanut processing companies, and the USDA Bureau of Human Nutrition and Home Economics, in general, indicated that both raw and roasted peanuts may develop off flavors from both Lindane and BHC under field applications at levels of around one part per million per acre. The quality of oil made from these peanuts has been evaluated for use in frenchfrying potatoes, and off flavor was noted in the first batch of potatoes fried, but not in the later batches.

Our own experience in the Southeast has confirmed that it is quite difficult to obtain peanuts with a BHC content less than 0.5 part per million from certain areas. In fact during the past year, we have found it difficult to keep up our production due to the long delay involved in sampling and analyzing various lots of peanuts prior to ultimate purchase. We have been unable to detect off flavor in commercial nuts at levels below 0.5 part per million, a value which is far below any tolerance that is apt to be established by the Food and Drug Administration due to the low chronic toxicity of BHC. We have preliminary evidence which indicates that peanut butter, containing over two parts per million BHC, exhibits some degree of off flavor after a 5-month shelf life.

There are certain basic considerations which have forced us to adopt a purchasing policy of rejecting all produce, which has been treated, during the formation of edible plant parts, with BHC or lindane, or which has been grown on soils contaminated by BHC or lindane. These may be summarized as follows:

(1) BHC tends to penetrate into the edible portions of some agricultural crops with which it comes in contact. This is particularly true of peanuts, and has already been discussed for them, as well as other crops.

(2) Due to penetration we have been unable to develop any washing, peeling, or inactivation procedure which will completely remove BHC residues or off-flavors resulting from its presence.

(3) Processing in many instances tends to accentuate the off flavor of BHC and lindane, and in certain instances off flavors continue to develop for some time after processing, while the produce is on the shelf.

It is very embarrassing, sometimes, to find after your stuff has gone out of your plant that you might have off flavors developing and get consumer complaints, so we have had to be very cautious about that one factor.

Bioassays and chemical analyses have revealed that this off-flavor is accompanied by a chemical breakdown of BHC to relatively nontoxic off-flavored materials of, as yet, unknown composition.

(4) BHC residues may remain in the soil for several years, and under certain conditions of continued application may tend to accumulate.

Our own surveys in the Southeast and in California have established considerable soil contamination by this compound. Research by the Bureau of Plant Industry (9) has indicated that BHC put in the ground in September 1946 persisted to December 1949 at 1/2 its original concentration; in other words, this means that BHC in some soils may have a half-life of 3 years. Good research, based on accurate analytical methods, is needed to determine at what rates BHC is accumulating in those cotton soils of the South where other food crops may be grown in subsequent rotations; as well as in other areas, especially California, where soil contamination is occurring.

(b) Chlordane: A review of the available literature on off flavors from chlordane largely confirms our own experience, that this insecticide, under certain conditions of use, may cause either an off-flavor, or a distinct difference in taste.

With respect to peaches and similar fruits, Chandler (4), in attempting to control plum cruculio with this compound, found that it conferred some off-flavor to both the raw and cooked fruit. Likewise, Gould et al. (10) noted off-flavors of canned Stanley-type plums and canned Elberta peaches resulting from somewhat excessive and late-season applications. Rings and Gould (19) found that chlordane controlled plum curculio on plums, but impaired the flavor of the fruit of at least one variety.

With respect to vegetables, Pepper (16) found that chlordane treatment of soils for wireworm control imparted an off-flavor to potatoes. This was later confirmed by Greenwood and Tice (11). The same year, Wheeler (24), warned in the Market Growers Journal that chlordane was similar to BHC, in that off-flavors were being reported on potatoes and some other root crops grown on soils treated with this material, and that the effect may persist beyond the season of treatment.

On snap beans, Ellis and Clayton (6) found that soil applications of chlordane for root-knot control imparted a disagreeable odor. Later Ristich and Schwardt (20) detected off-flavors in dried kidney beans, grown on soils treated with chlordane dusts for control of the seed-corn maggot.

Our experience with peaches, from experiments where chlordane was used late in the season in excessive amounts, indicates that it imparts a flatness of taste similar to lack of sugar. Experiments with other products to which known amounts of chlordane have been added prior to processing indicate also that chlordane did not contribute a

definite chemical off-flavor in itself; but rather, due to its presence, or that of its breakdown products, the taste buds were affected in such a fashion that their sensitivity to sweetness, and perhaps other taste sensations, were decreased.

By means of a qualitative odor test, or by other means, we have detected chlordane on California celery, New York cabbage, and New York carrots.

As yet we have no long-term data on the stability of chlordane in the soil. Preliminary reports from research started by the Bureau of Plant Industry (9) in 1949 indicate that chlordane may persist in a relatively unchanged form for at least 1 year.

(*c*) Other pesticides: We have experimental evidence from cooperative experiments in California that some of the dichlorophenol esters of benzene sulfonic acid, when used as miticides, have caused off-flavors in string beans, grapes, and unpeeled pears. Because of these and other miticides for which we had no method of analysis or previous history of off-flavor, we experienced a great deal of difficulty in the 1951 purchases of pears on the west coast. Our original purchase program called for between 1,000 and 1,500 tons of pears from California, but we were unable to complete this program because of the various miticides used. It was then necessary to purchase from the Yakima district in the State of Washington where, due to the higher price and added cost of transportation, we suffered a financial loss of between $20,000 and $30,000. We expect these materials to be used in considerable amounts according to California plans for this coming season. Therefore, unless satisfactory methods of residue analysis are developed we will be forced to contract for Yakima pears again. I might say that the State of Washington is far ahead of the rest of the States in an insecticide program which produces quality produce with minimum residues. We have always have the best of cooperation from the Big Y, the Washington State Apple Commission, and individual growers.

Recently on the west coast, we had an unusual experience with one of the common dithiocarbamate fungicides, which, heretofore, we had considered perfectly safe for use on all crops for which it had been recommended. In this particular instance, following an outbreak of peppermint rust in the Willamette Valley and along the lower Columbia River, we cooperated with Oregon State College on an experimental program aimed at finding some fungicide which would control this disease. Preliminary experiments indicated that certain of the dithiocarbamate fungicides would give partial control, but we felt it necessary to run complete chemical analyses on the peppermint oil, and then correlate the results with flavor panel tests on chewing gum. Much to our surprise, we found that steam distillation had brought about a chemical decomposition of the dithiocarbamates to produce over 400 parts per million of carbon disulfide in the peppermint oil. Subsequent flavor tests also revealed that this oil was off-quality, from the standpoint of odor and flavor. Unfortunately, some of the peppermint growers, who had heard of the favorable results obtained from the use of these fungicides, were persuaded to apply them to considerable acreages, much against the recommendation of Oregon State College. The result was that we were forced to reject the oil, even though we needed it very badly at that time.

At about the time we ran into trouble with these dithiocarbamate-type fungicides on peppermint, we found that certain English investigators (1) had reported that the presence of the spray residues of certain thiocarbamates stimulated the production of hydrogen swells in canned currants, and in some cases adversely affected the flavor. Concurrently, within the past few years, we have encountered a type of accelerated corrosion in our baby-food closures, which we think may be partially due to certain nontoxic thiocarbamate-type accelerators used for vulcanizing the rubber gasket of the closures. Since then, we have very carefully scrutinized all products for dithiocarbamate residues, not because of toxicity, but because of possible off-flavors and the possibility of closure corrosion.

THE COST OF MAINTAINING MINIMUM RESIDUES IN BEECH-NUT FOODS

The cost of maintaining our quality standards with respect to pesticides has been considerable since 1946. The following table gives a breakdown of this expense to ourselves and the consumer by years, since 1946.

The annual cost of pesticide control in Beech-Nut foods

Year	Research and quality control	Agricultural procurement	Processing losses	Special equipment	Total
1946			$51,000	$7,000	$58,000
1947	$35,000	$20,000	30,000	7,000	92,000
1948	55,000	20,000	30,000	7,000	112,000
1949	85,000	20,000	30,000	7,000	142,000
1950	80,000	20,000	30,000	7,000	137,000
1951	70,000	20,000	30,000	7,000	127,000
Total cost, 1946–51					668,000
Average per year for 6 years					111,333

The average annual cost of $111,333 per year is certainly a conservative figure, since we have had to direct the time and effort of our best research men to nonproductive problems, and have thus been deprived of their services in the development of new and improved products, which are the backbone of progress in a field as highly competitive as the food business. What does this mean to the final cost of our products? With peanut butter as an example, the cost of quality control and procurement for BHC-free peanuts amounts to 5 cents per dozen jars.

THE NEED FOR MORE AND BETTER COORDINATED RESEARCH ON PESTICIDES

Most of the difficulties with residues, which we have described, have been due to their general use before sufficient scientific information was available on residue stability, residue penetration, development of off-flavors in fresh or processed foods, their accumulation in soils, their effect on the over-all insect population, or the development of resistance in certain species of insects. The disturbed ecological relationships, which have often destroyed beneficial predatory insects, have allowed the build-up of other insect pests, which could not be controlled by normal spray procedures; this, combined with the de-

velopment of resistance to specific insecticides, has resulted in control programs which have caused the build-up of excessive residues in the hope of achieving control, and when this was unsuccessful, the hasty and often ill-advised use of new and more effective insecticides which had not yet been thoroughly tested. The net result has often been the creation of residue or off-flavor problems more serious than those arising from the use of the original insecticide.

It appears that some of the economic entomologists who have been active in the development of certain ill-advised pesticide recommendations, have tended to become chemical specialists, rather than entomologists. G. C. Ullyett of the Commonwealth Bureau of Biological Control, Ottawa, Canada (23), who is also an economic entomologist, says:

> Economic entomology is concerned with problems connected with insect populations which threaten the crops and produce of mankind. It deals with the control or limitation of those populations within the habitat in which they occur and is therefore primarily occupied with the problems which have an essentially ecological background. To be rational, therefore, the methods, employed in the course of its investigations, should be based upon a thorough cognizance of the ecology of the insect concerned.
>
> It follows that the economic entomologist should be thoroughly conversant with the principles, methods, and aims of ecology. Unfortunately, he is often lacking in the essential groundwork of this subject; or, if he has received adequate training, his professional career encourages him to ignore it in his daily work. He ceases to be a biologist and, in the majority of cases, becomes in effect, a mere tester of poisons or an insecticide salesman.

Along the same lines Paul DeBach of the division of biological control of the University of California, Riverdale, Calif. (5), says:

> Insecticidal treatments for citrus pests have developed as emergency measures in response to immediate problems. Although such treatments have made it possible to raise commercial citrus crops, this immediate need has led to the neglect of fundamental studies of natural factors affecting pest populations. In many cases such treatments have resulted in no final solutions to pest problems; rather, repeated applications have been necessary in order to maintain control. Such repetition of treatment may, indeed, serve in time to intensify the problem. Such a result may occur through (1) the development of genetic cases of a pest resistant to the insecticide used; and (2) the reduction of natural enemy populations by the insecticide used. The emergency then becomes self-perpetuating.

I wish to emphasize that the development of the new organic insecticides has largely taken place since the enactment of the current Food and Drugs Act, and that, by their very nature, they have created problems of misuse, which were not anticipated when the act was passed. We recognize that certain additional legislation may be necessary in order to adequately protect the public from undesirable residues. We are, also, of the opinion that such additional regulation could be kept to a minimum, if provision could now be made for a carefully thought-out and well-coordinated program of research, aimed at anticipating and avoiding future problems arising from the expanded use of current pesticides, or the use of ones as yet undeveloped.

Much of the testimony presented in the past before the food and drug hearings, and at those hearings being held by your committee, has been devoted to establishing the necessity for use of pesticides, and we are in favor of that—we need good, effective pesticides. On the other hand, very few of the agencies, or organizations involved in the development and use of these new compounds, have openly admitted that certain problems, similar to those encountered by our company,

exist. Nor have they offered a plan of action whereby they could be avoided in the future. I know that considerable funds have been raised to offset supposedly undesirable publicity against chemicals in foods. The action of your committee or other agencies, including those of us in the food industry who have felt that we were unduly burdened by the problems of pesticide residues, may have contributed to this feeling. On the other hand, it has been extremely difficult to raise funds, from either the food industry or the chemical industry, for research projects on residue problems in canned or processed foods. I admit that almost everyone is interested in attending committees formed to discuss mutual problems. Perhaps we have too many committees, all subject to pressure from special interests; but, be that as it may, most companies are loath to contribute money to a research project, no matter how well organized and supervised, which may show that a competitor's product has certain advantages superior to theirs. This is human nature, and should be recognized as a distinctly limiting factor to far-reaching cooperative research supported entirely by industry.

On the other hand, we are paying State and Federal taxes to support State experiment stations, and various bureaus within the USDA, such as the Bureau of Entomology and Plant Quarantine, which have and are taking the direct responsibility for testing and recommending various pesticides for use. We recommend, therefore, that, along with any proposal for new legislation, due consideration be given by Congress to the development of a coordinated program of testing between the USDA and at least four of the key regional State experiment stations. Each new pesticide, which shows promise of commercial use, should be thoroughly investigated in accordance with a definite plan of procedure with respect to methods of residue analysis, residues at times of harvest, off-flavors, methods of residue removal, stability of soil residues and their effect on crops, their possible effect on insect ecology, etc. If this could be achieved, most State recommendations could be made on a sound scientific basis, with corresponding protection to the farmer, the food processor, and the consumer.

With regard to toxicological testing, it would seem that a better coordination of research could be achieved, if the United States Public Health Service were empowered to expand their program in cooperation with the chemical manufacturers. The United States Public Health Service has the technical personnel, facilities, and experience for doing this work, and if properly administered, it would seem that they would be in a better position than the Food and Drug Administration to establish proper tolerances. We are firmly of the opinion, however, that the Food and Drug Administration should have full responsibility for the enforcement tolerances under either existing or future legislation.

THE BASIC REQUIREMENTS FOR CONTROL OF PESTICIDAL RESIDUES IN FOODS

With regard to legislation aimed at the control of pesticidal residues in foods, there are certain basic requirements which we consider essential; they may be summarized as follows—some of them are already taken care of under existing legislation:

1. Evidence of adequate toxicological testing.

2. The development of suitable methods of pesticidal residue analysis in order that the farmer, the food processor, and the consumer be protected against accidental or intentional misuse of toxic pesticides. The manufacturer of pesticides should be required to present a suitable method of residue analysis prior to registration for sale.

3. General information on the approximate range of residues occurring on or in produce at the time of harvest. This should include data covering adequate pretesting for off-flavors in fresh or processed foods.

4. Some general recommendations, based on the known chemical and physical properties of the pesticide as formulated, regarding the development of adequate methods for removing excessive residues.

5. A requirement that the Food and Drug Administration, once a pesticide is registered, establish and publish a tentative tolerance in the Federal Register, within 90 days following registration.

6. A requirement that following the publication of tentative tolerances, the Food and Drug Administration make sample analyses of interstate shipments of fruits and vegetables, and if the tentative tolerances are exceeded, issue public warnings to the areas of production concerned. In other words, we do not want to put the farmer at the mercy of any agency unless he has been given adequate warning.

7. A requirement that, if the tentative tolerances are still being exceeded after a 90-day warning period, the tentative tolerances be made official and seizure proceedings instituted.

Our idea there is to prevent the Food and Drug or whatever agency is concerned from dodging their responsibility.

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The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Cox, on page 3 of your statement you say that DDT and other related chlorinated hydrocarbons have forced you to adopt a near zero tolerance level in baby foods. Is that correct?

Dr. Cox. That is right.

Mr. KLEINFELD. In other words, you are trying to practically eliminate these residues from your baby foods?

Dr. Cox. True.

Mr. KLEINFELD. And in that connection you say on page 4 that you have given primary consideration to the evidence that young animals are usually more susceptible than older ones?

Dr. Cox. That is true.

Mr. KLEINFELD. And occasionally exhibit marked change in certain organs even though body growth may be normal, when subjected to the chronic effects of DDT and other chlorinated hydrocarbons. Is that correct?

Dr. Cox. That is correct.

Mr. KLEINFELD. You also say on page 4 that experiments have indicated that suckling calves are more susceptible to benzene hexachloride, toxaphene, and chlordane than older animals?

Dr. Cox. That is correct.

Mr. KLEINFELD. And you say, on page 6, that since you are primarily manufacturers of baby foods, you have had to take into account all the factors you mentioned—pre-natal, environmental, physiological, and structural—which may cause an infant, or a child, to react to food residues in a manner different than adults. Is that correct?

Dr. Cox. That is correct.

Mr. KLEINFELD. In other words, it is a more serious problem as far as children are concerned and particularly babies, than as far as the ordinary adult is concerned?

Dr. Cox. We feel it is.

Mr. KLEINFELD. That puzzles me somewhat, because a month or two ago at our hearings on the west coast when a representative of the National Canners Association testified, he was asked whether the standards of canners were different with respect to regular canned foods for adults than with respect to canned foods for babies, and he said the canning industry is trying to eliminate all residues.

And he was asked again, "Are you saying that the standards for both canned foods for adults and canned foods for babies are exactly the same?"

And this representative of the National Canners Association said, "Up to the present time I believe they are."

Apparently then, according to that representative, most of the canners are not taking any additional precautions with respect to their baby foods. Do you know whether that is correct or not?

Dr. Cox. I think perhaps we have more information on residues than the National Canners do, and I think for that reason maybe whoever made that testimony did not see the whole picture as we do.

Mr. KLEINFELD. If what he said is correct, do you not think it would be advisable to take even greater precautions with foods destined for babies than with foods destined for adults?

Dr. Cox. We use to be in the general food business. At the present time the only other food that we sell that is not strictly a baby food is peanut butter. We classify that, in our own thinking, as a baby food because it is primarily eaten by youngsters, and we have the same standards for our peanut butter. In coffee, our other product, we have not run into any trouble.

I don't feel qualified to speak for the rest of the canners. I don't know what their problems are.

I do know—and we are always on the alert for the development of new products—that if we developed a food for adults we would probably set about the same standards as we do for baby foods, for the simple reason the major portion of our purchasing program is for baby foods, and it would be very difficult to separate one from the other under a contract set-up.

Mr. KLEINFELD. As I gather your testimony, you do feel that because of the factors you mention in your statement it is rather important that you be very careful with respect to possible residues on baby foods?

Dr. Cox. Absolutely.

Mr. KLEINFELD. It is a different problem than the adult problem, is it not?

Dr. Cox. Very definitely so.

Mr. KLEINFELD. Does your company from time to time reject produce which you purchase?

Dr. Cox. A great deal.

Mr. KLEINFELD. Why do you ordinarily reject it?

Dr. Cox. In many cases we reject it because it does not come up to our quality standards in texture or appearance, or it has excess insect fragments, or too high a mold count, or because of residues or off-flavors.

Mr. KLEINFELD. Do you know what happens to the produce you reject at different times?

Dr. Cox. That is kind of a hard question—it has been sold.

Mr. KLEINFELD. Been sold?

Dr. Cox. Yes.

Mr. KLEINFELD. To whom? You need not mention any names. I mean to what class of persons?

Dr. Cox. Well, we have had repeated instances that other canners have bought our produce or it has been sold on the fresh market.

Mr. KLEINFELD. For sale to the consumer?

Dr. Cox. For sale to the consumer.

Mr. KLEINFELD. Do you make any product for babies which involves the purchase of chickens?

Dr. Cox. We do—chicken soup in our baby foods.

Mr. KLEINFELD. Do you have any policy with respect to buying chickens in which diethylstilbestrol has been implanted?

Dr. Cox. We have a very carefully worded policy which we have issued to all of our suppliers of chickens that we will not accept chickens on which stilbestrol has been used.

Mr. KLEINFELD. Why is that, Dr. Cox?

Dr. Cox. We have two very good reasons: One, in our chicken soup we are primarily interested in the protein and in flavor, and we have pretty definite information that indicates that most of the flavor comes from the protein portion of the meat. And along with that the pediatricians do not want too much fat in any of our foods because many infants, particularly with certain infant disorders, have difficulty in handling fats. So we do not want a chicken that is too high in fat, and we do know that stilbestrol does not increase the protein content of a chicken, it essentially builds up a high fat and water content which we do not want and we cannot use.

Our second reason is based on the same information that we have established for pesticides. We feel that infants who have all of the essential organs developing at a very rapid rate would probably be much more sensitive to these things than adults, and we know from past experience that these things have not been used properly, and we just don't want to take any chances.

Mr. KLEINFELD. On pages 6 and 7 of your statement, Dr. Cox, you state that the fragmentary data which you have been able to assemble to this date indicates at least that the new-born baby may already have a slight amount of DDT stored in its tissues. That is when he is born?

Dr. Cox. Yes.

Mr. KLEINFELD. And that he also may be receiving additional amounts via his mother's milk prior to the time he is ready for commercial milk or baby food.

Now does the fact that these infants already have DDT in their system mean we have to be less careful about adding DDT to the foods which they eat?

Dr. Cox. As far as our own company policy is concerned, we have to be more careful.

Mr. KLEINFELD. I say, does that mean you have to be less careful about adding it?

In other words, the fact that we may be unable, because of present practices, to avoid the presence of some DDT in some foods does not necessarily mean we have to throw up our hands and say, "Well, let's keep on adding it," and not take any precaution; is that right?

Dr. Cox. We have been able to stay in the baby-food business and obtain produce that by proper washing or peeling procedures is free of residues. And we feel that we can continue to operate that way, providing we have adequate information ahead of time on how to properly use new insecticides.

Mr. KLEINFELD. Are you in a position, Dr. Cox, to tell the committee why new-born babies at birth have DDT in their tissues, and why they are receiving DDT when they drink their mothers' milk?

Dr. Cox. The only information I have there is information that has already been given to the committee by the Food and Drug Administration and has since been published.

Mr. KLEINFELD. What is that?

Dr. Cox. Primarily the work of Dr. Lehman and Dr. Laug, who showed that certain amounts of DDT were present in the milk of mothers from a certain area, that DDT was accumulating in body fats, and that if it constituted at least 1 part per million in the daily diet there was very definite tendency to accumulate in body fat.

Mr. KLEINFELD. Apparently we are still finding DDT in new-born infants, and from the testimony we have had, we know that adults are also storing DDT in their bodies, notwithstanding that now at least, DDT is not being applied directly to cows or in dairy barns. Where do you think it comes from? Do you know?

Dr. Cox. We have to take into mind that their research and their data was obtained just about the time that the joint warning was issued by the Food and Drug Administration and the Department of Agriculture against the use of DDT on dairy animals or in dairy barns. And I do believe that warning has been pretty well heeded. I know it has in our area of New York, which is part of the New York milkshed, because we have been keeping close track on milk that we use from the Rochester area. I think at the present time, perhaps, if they were to repeat that work they would find the levels would be somewhat lower. But we are using that as an example of what can happen if an insecticide comes into general use before we have adequate information about all the factors that may be involved.

Mr. KLEINFELD. Do you think that when DDT came into general use we had all that information which you mentioned?

Dr. Cox. No.

Mr. KLEINFELD. On page 7 of your statement, Dr. Cox, you say:

> Certainly in the case of infants, where there is a relatively high proportion of body fat as compared with adults, we can take few chances with accumulated residues of DDT or other similar substances suddenly being released by one of many infant disorders which may cause sudden and appreciable loss of body weight through rapid fat metabolism.

Apparently from what you say there, that too is a greater problem as far as infants are concerned?

Dr. Cox. We think so. We don't have any direct data to support our view, but we think that from our observations on the high order of chronic toxicity with other young animals they apparently lack the ability to metabolize these things and excrete them.

Mr. KLEINFELD. If such a contingency occurs, that is, DDT suddenly being released in the blood stream of an infant when he is suffering from some illness, do you think we are in a position to say that the infant will suffer no ill effects?

Dr. Cox. We wouldn't want to have that happen to us and have to prove it in court.

Mr. KLEINFELD. Apparently we don't know, do we?

Dr. Cox. We don't know. But as far as our business is concerned, it is the type of risk that we can't take until we have more information.

Mr. KLEINFELD. And from the viewpoint of the infant I suppose it would be well to know that, too, would it not?

Dr. Cox. We believe that some research should be done along that line if at all possible.

Mr. KLEINFELD. On page 8 of your statement, Dr. Cox, you say that at the present time you have good analytical methods for DDT, DDD, benzene hexachloride, methoxychlor, and a few other insecticides, but you say, "unfortunately"—and I assume you are talking about the present time; is that correct?

Dr. Cox. That is right.

Mr. KLEINFELD. That satisfactory analytical methods for chlordane, toxaphene, aldrin, dieldrin, and heptachlor, which are in general use or may be used, are lacking.

Now, from the viewpoint of the canner, does that present a serious problem?

Dr. Cox. It presents a very serious problem, because we have found from our own experience that even on our contracted acreages it is almost impossible to completely supervise all insect applications, and a farmer may occasionally make the mistake of using the wrong insecticide.

We think that is what happened with our toxaphene experience on cabbage.

As another example, several years ago we had a rather large acreage of spinach contracted with a very reputable grower in Pennsylvania, on which he had agreed not to use benzene hexachloride. We had checked with field surveys, and we found they were not using benzene hexachloride, but were using rotenone instead. The first shipment of spinach that we received—at that time we did not have an analytical method that was accurate—was put in the cooker and it stunk up the whole plant, strictly BHC. We sent our field men back, we checked again, and they had not used BHC on the spinach, but they had been dusting broccoli with an airplane in adjacent fields, and it turned out there was a leaky hopper on the plane and they had been trailing BHC back and forth across the spinach field going to and from the airport and the broccoli field.

Mr. KLEINFELD. Suppose you were buying a vegetable, for example spinach, for canning for infants, and you found a residue of chlordane on it, what would you do about it?

Dr. Cox. We would destroy it.

Mr. KLEINFELD. And yet you say you don't have a satisfactory analytical method for chlordane; is that correct?

Dr. Cox. We do not have a satisfactory method. We what we call a quick odor test which at one stage of our DDT analysis will indicate the presence of large amounts of chlordane. But that is a very dangerous thing to do, because there could be cases where we wouldn't detect it. And we are now at the mercy of anyone who might use chlordane without prior knowledge.

Mr. KLEINFELD. Is it not a fact that many growers of vegetables and fruits, may use more than one insecticide?

Dr. Cox. Quite possible, yes; and it is also quite necessary in many cases.

For example, on apricots in California we found it satisfactory to use DDT or DDD early in the season, but after a certain date it has been advisable to use parathion because it doesn't give a residue at harvest time.

Mr. KLEINFELD. Suppose a grower in the course of the growing season has used both DDT and chlordane, does that affect the problem at all?

Dr. Cox. We can detect the DDT, but we still can't detect the chlordane.

Mr. KLEINFELD. Suppose he had used chlordane and toxaphene, does that add to the problem?

Dr. Cox. It would be very difficult to detect either one.

Mr. KLEINFELD. Would that make it more difficult to detect either one?

Dr. Cox. Yes, and that is the reason we have set up this long-term project at Boyce Thompson Institute in the hope of developing the bio-assay method.

Mr. KLEINFELD. That is still in the experimental stage?

Dr. Cox. It is in the practical stage as far as a research tool is concerned. It is a time-consuming procedure, but it could be used if you were doing experimental work on various insecticides in carefully controlled field plots where you have the time to collect the material and run the analyses. But it is entirely impractical at the present time for use in quality control in a plant like our own where you have to make the analyses within 24 hours.

Mr. KLEINFELD. Dr. Cox, beginning on page 11 of your statement you mentioned your experiences with off-flavors, particularly from BHC and lindane; is that correct?

Dr. Cox. That is right.

Mr. KLEINFELD. Have you had to turn down various quantities of fruits and vegetables because of the use of those insecticides and the consequent off-flavor?

Dr. Cox. Every year.

Mr. KLEINFELD. That has caused quite an economic loss to those farmers, has it not?

Dr. Cox. It has caused an economic loss to the farmers and to ourselves, and it has not been conducive to good canner relations.

Mr. KLEINFELD. Are you in a position to tell the committee whether, before BHC and lindane were put on the commercial market, information as to their possible characteristic of imparting an off-flavor to the produce was required of the manufacturers of those insecticides?

Dr. Cox. That I don't know.

Mr. KLEINFELD. On page 20 of your statement you specify the cost of maintaining minimum residues in the foods canned by the Beech-Nut Packing Co. As I see these figures, for the period from 1946 to 1951 you spent, you say, $668,000?

Dr. Cox. That is correct.

Mr. KLEINFELD. And you say that in your opinion that is a conservative figure?

Dr. Cox. Yes, it is.

Mr. KLEINFELD. On page 21 of your statement you make a statement which is particularly interesting. You say that most of the difficulties with residues which you have described have been due to their general use before sufficient scientific information was available on residue stability, residue penetration, development of off-flavors in fresh or processed foods, their accumulation in soils, their effect on the over-all insect population or the development of resistance in certain species of insects.

Dr. COX. That is correct.

Mr. KLEINFELD. So that, as I understand your statement, at least some of the insecticides were permitted on the commercial market before the factors which you mention were explained satisfactorily; is that correct?

Dr. COX. I would say that they were used by the grower before the grower had sufficient information as to how to use them properly.

Mr. KLEINFELD. Do you know whether the present Insecticide Act requires information on residue stability before an insecticide is permitted registration?

Dr. COX. I don't know.

Mr. KLEINFELD. Do you know whether the Insecticide Act requires information on residue penetration before a proposed insecticide can qualify for registration?

Dr. COX. I understand in verbal discussions with some of the people in the Insecticide Division that they have attempted to obtain as much of that information as was available before they made a decision. I don't know whether it is a general rule or not, but I know they are making a very conscientious effort to obtain that information.

Mr. KLEINFELD. Do you know whether they are requiring that because the law requires such information be furnished or because they are trying to do a good job?

Dr. COX. I think it is because they are trying to do a good job.

Mr. KLEINFELD. Do you know whether the Insecticide Act requires that information with respect to the development of off-flavors be furnished to the Department of Agriculture before a proposed insecticide is registered?

Dr. COX. That I do not know.

Mr. KLEINFELD. There have been large numbers of publications issued by various governmental bureaus concerning the employment of methods of chemical control of the insecticide problem. That is correct, isn't it?

Dr. COX. That is right.

Mr. KLEINFELD. Do you know of any publications which have been issued by any bureau or agency of the Government concerning biological methods of control?

Dr. COX. I know of several publications that were issued prior to the advent of DDT, and I do know that some work has been done and been published on biological control of certain insects for which we do not yet have adequate chemical control. But I do not know of any work that has been published on a really thorough-going basis covering the interrelationships between biological control and chemical control which we think needs investigating.

Mr. HORAN. What do you mean by biological control?

Dr. COX. Insect parasites.

Mr. HORAN. Like ladybugs?

Dr. Cox. Yes; predators and parasites, both.

Mr. KLEINFELD. Dr. Cox, on the bottom of page 21 of your statement, you say that—

> The disturbed ecological relationships, combined with developments of resistance to specific insecticide—

and we have had some testimony to that effect—

> has resulted in control programs which have caused the build-up of excessive residues in the hope of achieving control, and when this was unsuccessful, the hasty and often ill-advised use of new and more effective insecticides which had not yet been thoroughly tested.

You say that the net result has often been the creation of residue or off-flavor problems more serious than those arising from the use of the original insecticide. Is that corect?

Dr. Cox. Yes.

Mr. KLEINFELD. Well, that presents a pretty difficult and serious picture, doesn't it, Dr. Cox?

Dr. Cox. It does.

Mr. KLEINFELD. On page 22 you say:

> It appears that some of the economic entomologists who have been active in the development of certain ill-advised pesticide recommendations have tended to become chemical specialists rather than entomologists.

Could you explain that in greater detail, Dr. Cox?

Dr. Cox. Well, I can speak from personal experience within the past 6 months. When we sat in with the entomologists and research staff from one of the State experiment stations, one entomologist who had made certain recommendations that had gotten both the growers and ourselves into trouble, got up and made the statement, "Well, all of these new insecticides are coming on the market. As each one comes along I feel the responsibility to make recommendations for them."

The director of the experiment station got up and he said, "We will establish a policy right now that we will make no recommendation for anything until we have had adequate scientific information on which we can base those recommendations."

Because of the activities of this entomologist and one or two others who made ill-advised recommendations, we have discussed the problem of chlordane in carrots, where we showed that there was penetration. The farmers used it in a certain area, and we understand that crop had to be destroyed in the warehouse. Also we found in a certain State apples were contaminated with BHC. Since then those recommendations have been withdrawn.

Mr. KLEINFELD. Which insecticides have you found to have a penetrating effect? Are you in a position to say?

Dr. Cox. We have very definite proof for both lindane and benzene hexachloride. We know that there is some sort of a flavor penetration from chlordane in the carrots. We have no definite proof as yet from the chemical or bio-assay that it goes into the carrot tissue. We know that when carrots are carefully washed according to our washing procedure there is chlordane still on or in the carrots, but we haven't taken the research far enough to know whether it is a direct penetration.

Mr. KLEINFELD. Dr. Cox, on page 22, you have made a distinction between an economic entomologist and a chemical specialist. What

do you think the function of an entomologist should be as distinguished from a chemical specialist?

Dr. Cox. Well, I think that an entomologist—and I am following pretty closely the thinking of Dr. S. A. Rohwer, former Assistant Chief of the Bureau of Entomology and Plant Quarantine, who verbally issued warnings in many meetings, that entomologists should cease to be chemical specialists, that they should look at the insect in relation to his entire environment, including other parasites, other predatory insects, and in developing any chemical-control program they should make a thorough study of the effect of the insecticide on the soil and on other insects that may control the one we are trying to control. And I think one good example of that is our experience with the outbreak of the red-banded leaf roller in New York some years ago. I believe it has already been discussed before your committee.

In the attempt to control the codling moth they killed off the natural predators of the red-banded leaf roller and allowed it to develop to the point where it caused serious economic losses. That year we had to go clear into Nova Scotia to buy apples because we couldn't get the quality of apples we wanted in the Hudson Valley.

I think the Northwest has had a similar experience in the codling moth with relation to some of the mites up there that have increased and caused trouble.

Mr. KLEINFELD. As I understand your statement, the function of the entomologist is not merely to develop a substance which will kill an insect?

Dr. Cox. That is right.

Mr. KLEINFELD. On page 24 of your statement, Dr. Cox, you say that you know that considerable funds have been raised to offset supposedly undesirable publicity against chemicals in foods.

That is a very interesting statement. Could you explain that?

Dr. Cox. Well, practically all the chemical-trade journals and all the trade journals in the past month have included very widely publicized statements that a certain organization has been raising funds to counteract unfavorable publicity on chemicals in foods. They are not a bit bashful about saying it. There have been some very pointed statements made at your own committee about some of your activities that they would like to bring under control.

Mr. KLEINFELD. And undesirable publicity concerning the use of chemicals in foods would be testimony such as yours, indicating that perhaps some problem exists with respect to the use of chemicals on or in foods?

Dr. Cox. We have been accused of being hysterical about the problem; that is right.

Mr. KLEINFELD. Food faddists perhaps?

Dr. Cox. I think so. In fact, as a result of some of the publicity that has been given to chemicals in foods, we have had criticisms from the opposite end. We have had mothers write us letters accusing our company of using chemicals in foods.

Here is a letter from St. Petersburg, Fla.:

> It's the same old tale: The public be damned until it harms the health of the people by chemical additions to its food products.

She was writing to us in relation to peanut butter in which we used hydrogenated peanut oil in small amounts.

Mr. KLEINFELD. Dr. Cox, concerning the subject we just discussed, are you familiar with the fact that there was a meeting a week or two ago in New York of the Manufacturing Chemists' Association?

Dr. COX. That is right.

Mr. KLEINFELD. Did you attend?

Dr. COX. I did not.

Mr. KLEINFELD. Do you know what that was about?

Dr. COX. I have read their agenda very carefully, and it was supposedly aimed at a joint discussion between people in the food industry and people in the chemical industry about the problem of chemicals in foods.

Mr. KLEINFELD. Mr. Chairman, I have here a copy of a statement which was proposed to be given at that meeting by Dr. R. C. Newton, vice president of Swift & Co., which discusses some of the points which are frequently raised concerning the problem of the addition of chemicals to foods. In view of Dr. Newton's position as vice president of Swift & Co. and their position in the food field, I suggest it be made a part of the record. It is a short statement. This was forwarded to me as a copy of the statement that Dr. Newton proposed to give at this meeting but was unable to do so.

Mr. JONES. You say it was not given?

Mr. KLEINFELD. No; it was not given. It was a statement he proposed to give and was unable to give at that meeting.

The CHAIRMAN. Who forwarded it?

Mr. KLEINFELD. It was forwarded to me by a representative of Dr. Newton. Specific permission was given by him to put it in the record.

The CHAIRMAN. There is no objection on his part?

Mr. KLEINFELD. No objection.

Mr. JONES. You have word from Dr. Newton that he has no objection to its being put in?

Mr. KLEINFELD. He has no objection.

Mr. JONES. As long as it comes from him, all right. I do not think it should come from someone else.

The CHAIRMAN. Off the record.

(There was discussion off the record.)

The CHAIRMAN. If there is no objection, we will make it a part of the record.

(The statement referred to is as follows:)

SWIFT & CO.,
Chicago, Ill., January 22, 1952.

Mr. VINCENT A. KLEINFELD,
Chief Counsel, Committee to Investigate
the Use of Chemicals in Food Products,
House of Representatives, Washington, D. C.

DEAR MR. KLEINFELD: You have undoubtedly seen many of the printed statements regarding the chemicals-in-foods controversy. At the joint meeting of representatives from the chemical industry and the food industry, sponsored by the Manufacturing Chemists' Association, which was held in New York on January 15, there should have been an opportunity to properly review both sides of this question. It was my intention to present a prepared statement but because of a very crowded program the chairman allowed time to sketch only a few of the pertinent points. It seems worthwhile, therefore, to send to those in attendance at the meeting, and some others who may be interested, a copy of this brief statement.

There is considerable danger that the present situation will lead to a disaster which, in addition to the harmful effect on public health, will undermine public confidence in the food industry and particularly in the chemical industry. There

is a gap in the present Federal food law which should be closed by amendment. For foods that are as yet unstandardized, the present law places the burden on the Food and Drug Administration to prove that a substance is poisonous before its use in food can be prevented. A simple change in the law to place the burden of proof on the prospective user is essentially all that is needed.

I wish to make it perfectly clear that I have taken no position either in support or in opposition of any particular bill. It is because I feel so strongly that the chemical industry may do immeasurable harm to the food industry as well as to itself by opposing such an amendment, that I take the time to bring this matter to your attention.

Very truly yours,

ROY C. NEWTON.

STATEMENT PROPOSED TO BE GIVEN BY DR. R. C. NEWTON, VICE PRESIDENT OF SWIFT & CO., DURING THE DISCUSSION PERIOD FOLLOWING THE ARRANGED PROGRAM IN NEW YORK ON JANUARY 15, 1952, OF THE MANUFACTURING CHEMISTS' ASSOCIATION, ENTITLED "INTERINDUSTRY CONFERENCE ON CHEMICALS IN FOOD"

I am glad to have had the opportunity to sit in on this conference and hear the many diverse views on this important question. This subject is of tremendous importance to the food industry, and while it may be of considerable importance to the chemical industry, it occupies there perhaps only a minor role. The food industry of this country is immense. When considered on the basis of tonnage or dollar sales, the figures are tremendous. When reviewed from the point of view of numbers of producers, processors, and distributors, it is equally large; but, when viewed from the standpoint of the dependence of the American people for their very lives, it reaches its peak of importance.

No one company nor, in fact, no one segment of the industry can be considered as representative of the food industry in its entirety. There are, however, some problems which are common to a very great extent across the entire industry. There are certain responsibilities which fall directly upon any person who processes or distributes food to the public.

One of these responsibilities is to see that the food product reaches the ultimate consumer in a condition that will provide nourishment and, at the same time, present no hazard from its consumption. The fulfillment of this responsibility requires not only facilities but also a great deal of technical knowledge and, above all, a high standard of ethics for public welfare. There are many companies in the food industry who have sufficient technical knowledge; there are also many that subscribe to such high standards of ethics; and we hope there are increasingly more who can qualify on both scores.

The manufacturing chemical industry, under whose sponsorship this meeting was called, has made a brilliant record in the production of new and useful things for the betterment of mankind. One of the outstanding characteristics of this chemical industry is the speed with which new developments are adapted to human needs. However, in the application of science to food, speed is of less importance than safety.

It is not clear from the publications emanating from the chemical industry over the past 2 years that many of the members of this industry understand why a new material cannot be adapted to the food industry as quickly as it can to plastics, textiles, etc. The tone of many articles appearing in such sequence as to indicate direct propaganda have been obviously prepared by persons who do not have full realization of the delicacy of balance of chemical reactions within the human body and the ease with which foreign substances can throw this delicate mechanism out of balance.

Running through this series of propaganda articles are many unsound premises. The repetition with which these same erroneous issues appear would indicate a planned objective of confusion. I should like to mention five of these issues:

The first and perhaps the most frequent is that of natural versus synthetic. There are those among these writers who would have us believe that the issue centers around this point. I should like to deny emphatically that this question has anything whatsoever to do with the problem of chemicals in food. Surely no one denies that many substances growing in nature are poisonous to the human being. So that once and for all we can say that it makes no difference whether a poison is natural or synthetic; it still should be kept out of food.

The second erroneous issue is that of persecution. There is a vein of implication in many of these articles that the manufacturing chemical industry is being persecuted. Insofar as I know, this is also false and should have no part of the real consideration of this important question.

The third confusing bit of philosophy is that all foods are chemical in nature. Of course, they are all chemical in nature, but that does not lead to the conclusion that all chemicals are satisfactory as foods.

No. 4: You cannot prove a negative. This has been used to belittle the requirements for an adequate animal-testing program before new and unusual substances are allowed in food products. Whether you can prove a negative or not is beside the point, for you can get good substantial evidence that a substance is poisonous, the extent of its poisoonus quality, and the hazard presented by its incorporation in food. You cannot always do this in a few weeks. It is a 2- to 3-year program; and, since it is usually begun only after a thorough screening of a large number of substances, the total time very often runs to 5 or 6 years. With the rapid rate at which new substances are proposed for incorporation in foods, is this too great a penalty to pay for the safety of the public? I contend that it is not.

The fifth of the confusers is that even table salt is poisonous under some conditions. I think it is well established that one can cram enough table salt down his throat to kill him, but is there any doubt in the mind of anyone here that table salt used by the normal individual in the manner which it has been used for thousands of years represents any hazard.

Conversely, is there any doubt in anyone's mind that it is possible to incorporate in food products small amounts of chemical substances which, without being obvious to the consumer, would either kill him or impair his health when consumed over a long period of time?

The real issues and the only issues that are worth discussing in connection with this problem at the moment relate to pretesting of new and unusual substances proposed for food. I would like to list them in the order that they occur to me:

1. Shall the unusual products proposed for use in food (be it natural or synthetic) be subjected to animal testing before trying them out on the public? It is my experience that no one is bold enough to stand up in meeting and suggest that all these unusual substances be tried on the public without pretesting. Many, however, will have certain qualifications they wish to put in. They will object to the long test period. They will object to the levels that are included in the test. They will object to the interpretation of results. They will object to delegating authority to a Government body to serve as a referee on the adequacy of such tests.

2. Should such pretesting by compulsory? There are many who will laud the ethical standards of the chemical industry and the food industry in an attempt to show that they are reliable and intelligent enough to make all the tests required without compulsory action. A moment's reflection on the part of anyone should convince him that this is not true.

3. What constitutes a good and sufficient test? It is my own opinion that there is a lot yet to be said on this point. The Food and Drug Administration has attempted to outline the test requirements. They have recognized that each individual case calls for some modification and it is possible that as the years go on we will arrive at a clearer understanding of what should be required to protect the public.

4. Who should decide when the testing has been adequate and that the product is harmless? There are those who have proposed establishment of an unbiased, non-Government scientific body to referee these questions. It seems obvious to me that such authority can only be delegated to a Government appointee, and that brings us right back to the present regulatory bureaus in the Government. One of these is the Meat Inspection Division of the Bureau of Animal Industry. This regulatory Bureau now has all of the authority to require pretesting. The Food and Drug Administration has authority to require pretesting on anything to be added in those foods on which standards and definitions have been promulgated. It does not have authority, under the present law, to require pretesting on a proposed additive in a nonstandardized food, nor does it have authority to stop the use of that additive unless it can prove that the additive is deleterious. Since this is obviously an impossibility, as the Food and Drug Administration could not maintain a staff large enough to test all of the chemicals that can be thought up by the manufacturing chemical industry and the entire food industry, it seems only logical that the burden of proof should be reversed and put upon the industry rather than upon the Government.

I notice in the December 24 issue of Chemical and Engineering News that the Manufacturing Chemists' Association has raised a sum of money for public-relations activity. This article states that the contributions were made "because

of the emergency nature of the chemicals-in-food problem." I am particularly interested in this activity of the Manufacturing Chemists' Association because I have spent all of my business life in the food industry, and feel that I have a real stake in any matter that may affect the food industry. If I may judge from the numerous articles and editorials occurring in the chemical journals during the past year, I believe there is a real threat to the food industry. I base this assumption on the possibility that these articles, which appear in such sequence of repetition that they appear to be propaganda, may eventually affect public opinion to such an extent that the Food and Drug Administration will be prevented from carrying out its responsibility of protecting the public. If this series of events should come to pass, there will undoubtedly be a surge of new chemical substances incorporated in food without adequate pretesting.

Such a program will lead to a disaster, just as surely as we are assembled here today. Such a disaster will reflect discredit to the food industry; incidentally, it will also reflect discredit to the chemical industry, but the principal damage will be done to the public. After such a disaster there is no doubt that the law will be strengthened in any manner considered necessary for public safety.

With these hazards to public health and this threat to the prestige of the food industry as well as the chemical industry, is it too much to hope that the Manufacturing Chemists' Association in their public-relations program will do nothing to inhibit the Food and Drug Administration in its effort to protect public health? Also, may we hope that part of the activity of the Manufacturing Chemists' Association will be directed toward the education of its own members who may not understand clearly their responsibilities.

Mr. KLEINFELD. I have no further questions of Dr. Cox, Mr. Chairman.

The CHAIRMAN. Mr. Jones?

Mr. JONES. I was interested in this same thing that you discussed a minute ago; that you know considerable funds have been raised to offset supposedly undesirable publicity against chemicals in foods.

What group is raising those funds? What class?

Dr. COX. From the information that we have been able to gather from the recent articles in the newsletter of the American Chemical Society, they were apparently raised from the membership of the Manufacturing Chemists' Association.

Mr. JONES. Well, I mean you made the statement that you know that considerable funds have been raised.

Dr. COX. Yes.

Mr. JONES. Then you say you understand.

Dr. COX. Well, we do know. They have published it and told us.

Mr. JONES. You do know?

Dr. COX. They have published the figures.

Mr. JONES. You don't know what the amount is that was raised by them for that purpose?

Dr. COX. The last figure I saw was something like $119,000. I believe it has been roughly within that range.

Mr. JONES. One thing I was interested in is your statement about the tests on the spinach. Now when are those tests made on the produce? In other words, how quickly after the produce is brought into the plant are those tests available so that you know whether or not the produce is suitable for use?

Dr. COX. We go beyond that stage. We send our field men out and they make field samples prior to harvest and send them in for analyses, and we accept on the basis of this analysis, and they come into the plant. When they get into the plant they are analyzed again, and if there has been any mistake, the material is destroyed right there.

Mr. JONES. That would be just within a few hours?

Dr. Cox. Within a few hours.

Mr. JONES. I might say, as you know, some of the committee did have the opportunity to go through one of your plants in California.

Dr. Cox. Yes.

Mr. JONES. And I think that the company is to be commended for the precautions which they take. I was impressed, and I know prior to that time I had no idea of the precautions that were taken to eliminate the hazardous chemicals from appearing in the food products.

Now one other question, you have spoken here in the early part of your paper about DDT. Do you know what harmful effects have been noted from DDT in infants? You say that you know that DDT does appear in new-born infants. Do you know of any harmful effects that have been caused from that?

Dr. Cox. I did not say that I knew that DDT appeared in new-born infants, but from the information that is available we would make a calculated guess that it did.

Now we do not know of any injuries to infants as a result of eating foods contaminated with DDT residue. Neither do we intend to take any chances on finding out.

Mr. JONES. In other words, you are just using the maximum precautions?

Dr. Cox. We are.

Mr. JONES. Now what I have been trying to find out since this committee has started—we have heard a lot about DDT and about it being stored in the fat and other organs, but I haven't been able to learn what specific harmful effects have actually been caused by that DDT. That is what I have been trying to get.

Dr. Cox. We have no information on harmful effects from DDT in infants.

Mr. JONES. I have no other questions.

The CHAIRMAN. Dr. Miller?

Dr. MILLER. Dr. Cox, I think you have made a very fine statement, and I am glad you were able to appear before the committee, as we thought you might when we saw you in California.

I am interested in these chemicals in foods. You would not want to leave the impression that chemicals themselves in food are bad? In other words, if the chemical has been properly tested and there is no harm to the human being, you would not have any objections to the use of chemicals in foods to preserve the food, make it look better, and maybe add something to it that nature had left out?

Dr. Cox. We have had practically no experience with the addition of chemicals to foods. But in the development of new products which we anticipate, if we had to add such a chemical to maintain the quality of the food or give it proper nutritive value, we would very definitely want to have all the information available.

Dr. MILLER. In other words, if there is no harm to human beings in introducing it in the food stream you would have no objection to it?

Dr. Cox. Absolutely not.

Dr. MILLER. I was thinking of certain vitamins that might be added to food, such as cod liver oil products. And in animals' food, they are adding aureomycin to the food of hogs to get rid of intestinal parasites, and it seems to do something to the hog, he gets over illnesses quicker.

Dr. Cox. We still feel that a lot has to be known about the possible effects of antibiotics before we are ready to accept them for use in the food business.

Dr. MILLER. I think that is well.

What about the natural enemies of the old codling moth and grasshopper and other rust mites, and so forth—is work being done on developing natural enemies of the codling moth instead of using pesticides?

Dr. Cox. Some work is being done, but we agree with some of the economic entomologists who recently had a symposium on biologic control, that a great deal more work needs to be done. We feel it should be carried out concurrently with the development of new pesticides. We feel it is a field that has been a bit neglected due to the pressure of finding out how you can use chemicals, and we think that work has to be revised.

Dr. MILLER. I noticed in some of your recommendations on page 26, particularly on pesticides, that the manufacturer of pesticides should be required to present a suitable method of residue analysis prior to registration and sale.

Would you put the entire cost upon the manufacturer of pesticides to determine and present to the Food and Drug Administration what effect the pesticide might have, the residue, and so forth.

Dr. Cox. We think such a method is absolutely necessary, but I can conceive of instances where a very effective insecticide may be developed and we would need it very badly, and it may be a small chemical manufacturer, and I think some provision should be made that he get help from elsewhere if he needs it. I know our company has cooperated with some of the chemical manufacturers in developing methods. We developed the original method for methoxychlor now widely used, and we developed a method for benzene hexachloride.

Dr. MILLER. Do you think the responsibility should be placed entirely in the Food and Drug Administration or would you put it some place else—Public Health or Agriculture?

Dr. Cox. Responsibility for what—developing methods?

Dr. MILLER. Or administering the law, checking on the toxicity of the pesticide or chemical fertilizer that might be used.

Dr. Cox. I have already covered that in my statement.

Dr. MILLER. You have covered it. I came in a little late and read it over hurriedly and did not cover all of it.

Dr. Cox. I have been very careful in what I have said, because I know nothing about the food and drug law. I make no pretense to be an expert on that line.

Dr. MILLER. On page 27, article 6, you say:

A requirement that following the publication of tentative tolerances, the Food and Drug Administration make sample analyses of interstate shipments of fruits and vegetables; and if the tentative tolerances are exceeded, issue public warnings to the areas of production concerned.

Dr. Cox. Yes. We think that that is necessary in order to adequately protect the farmer. We feel that the farmers have sometimes used insecticides without being adequately informed, and we found from our own experience if you issue a warning to them, they attempt to do something. We think that it would be very bad for for exam-

ple, an area in the Northwest to start using something and have a seizure without any warning whatsoever. And if they are warned by an official agency that action will be taken unless they do something, it gives them a chance to get their house in order.

Dr. MILLER. It would be a tremendous job to go over all of the chemicals proposed to be used in food, pesticides and other things that go into the food channel. It would take quite a force to properly analyze and carry out experiments.

Dr. COX. Well, my testimony is confined only to pesticides.

Dr. MILLER. I think that is all.

Mr. HORAN. I also enjoyed your statement, Dr. Cox, particularly your reference to the State of Washington and the experience that we have had through the years with insecticides and their removal, and what constitutes a proper regulatory system.

But I am a little bit confused about all seven of your points here, because I think the question is, is it not, who should set the tolerance?

Dr. COX. Well, I am not an expert in legislative matters and I don't feel competent to say that.

Mr. HORAN. That would be administrative, I should think.

Dr. COX. We do feel this: That as taxpayers in the interest of saving money the United States Public Health Service already has the technical personnel and the facilities for doing much of the research on toxicological testing on which tolerances could be definitely established, and we would certainly like to see the Public Health Service put in a position to do that work. It would avoid undue duplication of effort.

Mr. HORAN. That, of course, coincides with my own thinking.

Dr. COX. In other words, I am thinking pretty much along the lines that Cliff Chase presented in his testimony at Spokane.

Mr. HORAN. I notice here with a good deal of interest in the statement supplied to us, not made public yet, Mr. Kleinfeld, that Dr. Newton would appear to have that same basis of conclusion. He is like most scientists, of course; he beats around the bush quite a bit. I wish he was here so we could hear him say that.

Do you not think a program that would have an unbiased body, under close supervision by the Public Health Service, if it were a private body such as the American Medical Association committee on cosmetics, authorized to declare what is safe and what might be deleterious to the public health, or else have the Public Health itself conduct those experiments as is now being conducted in Savannah, Wenatchee, and Seattle?

Dr. COX. We would have more confidence in the Public Health Service doing the basic research than we would in some private body doing it, because it is a little further removed from under pressure from special interests.

Mr. HORAN. That raises a very interesting case that this committee has attempted to deal with, and that is in the case of cosmetics, which are an essential but not a necessity of life, should the public pay for the setting of these tolerances and the experimentation that might be needed? And if you didn't think that the taxpayers of the Nation should shoulder that responsibility and that cost, how would you go about it to see that some quasi-public body was certified to conduct those tests and have them stand up after they had been conducted?

Dr. COX. With respect to pesticides——

Mr. HORAN. I am talking now about the committee on cosmetics set up under the American Medical Association, who have a sort of laboratory out in Chicago that does offer its services to the cosmetic industry. I will get back to foods, but I want your feeling in this matter first. At this laboratory they apparently do not conduct too much experimentation, but they do assemble the known facts and issue the conclusions, as I understand it. Is that not right, Mr. Kleinfeld?

Mr. KLEINFELD. They do some testing.

The CHAIRMAN. Along that line.

Mr. HORAN. Along that line.

Now do you feel in the case of cosmetics, which are an essential but not a necessity of life—people can live without them—do you feel that the taxpayers of the Nation should foot all the bill, or what procedure might be entered into to enable cosmetic manufacturers—and they are honorable men—to offer their products safely to the public?

The question is, Should the taxpayers pay for that sort of experimentation?

Dr. COX. I do not feel competent to express an opinion on that because I don't know the background.

Mr. HORAN. That is all right.

Now in the case of food which is a necessity of life—we have to eat to live—do you feel that the Public Health Service should be employed to conduct experimentations on these things?

Dr. COX. With regard to pesticides, I still think most of the burden should fall on the manufacturers who want to sell these things. But there are many instances with which we are familiar that certain special tests have to be done, there are certain points of information to complete the picture that have to be gathered that the pesticide manufacturer does not have the facilities or cannot get the facilities for doing, and we think that in those cases, in order to bring the picture into focus, that the Public Health Service should have facilities for doing that. They have already set the pattern on hazards to the operator. There are certain questions which have come up that the chemical manufacturer found impossible to handle, because they were regional problems, and it was for that reason that the regional laboratory was set up at Wenatchee, we think that is a very healthy expenditure of public funds in the public interest. Those are the type of things we are thinking of.

Mr. HORAN. Well, that follows along my thinking, but we do have to, I think, separate the various things in channels of commerce that might be deleterious to the public health, and we have to set up a pattern of pretesting them before they are offered to the public, and that involves laboratory work, involves experimentation and a lot of other things. And don't you feel that if we arrive at any conclusion at all that we should be able to say in the case of foods, which the public needs, we feel that it is a proper expenditure of taxpayers' funds to conduct this sort of thing the same as we are doing at Wenatchee with pesticides?

Dr. COX. Within that definition; yes.

Mr. HORAN. But in the case of those things which are not too highly essential to the public health we feel that a greater amount of the burden should be carried by the industry itself. Is that a logical differentiation?

Dr. Cox. Your statement sounds logical to me within my limited knowledge.

Mr. HORAN. That is all, Mr. Chairman.

The CHAIRMAN. On page 1 of your statement you refer to mold counts.

Dr. Cox. Yes, sir.

The CHAIRMAN. Could that be helpful in determining whether fungicides, pesticides, or insecticides were used?

Dr. Cox. Well, to begin with, the Food and Drug Administration has already set very definite tolerances for mold count, and if we exceed those tolerances we know we are going to be subject to a seizure. So we know how we have to operate there. And it gives me an opportunity to emphasize the very definite need for good pesticides that we know how to use, because unless we can use good fungicides and keep the mold count down, say, on tomato products, we are going to run into trouble with an inferior product that the Food and Drug Administration is not going to hesitate to make the seizure on.

The CHAIRMAN. Well, even if no pesticide or chemical of any kind were used, you could still have a full mold count?

Dr. Cox. Yes.

The CHAIRMAN. If the product was aged. It is a natural process, is it not, in most foodstuffs?

Dr. Cox. No.

The CHAIRMAN. It is not?

Dr. Cox. It is the mold count in the material at the time it is processed. After you go through your processing procedure and sterilization you get no further development of molds provided your container doesn't leak. If you run into leakage you are going to run into seizures again.

The CHAIRMAN. Are you able to determine from the mold count whether chemicals of any kind were used?

Dr. Cox. No; we are not.

The CHAIRMAN. Or the reverse?

Dr. Cox. No.

The CHAIRMAN. All right. Now, in the past when they used chemicals on, for example, a product like cotton, they did not have to be too careful about the quantities used except for economic reasons. Today, however, don't we get cottonseed oil from cotton, and isn't that used in oleomargarine?

Dr. Cox. Yes; certain proportion and certain types of oleomargarine have hydrogenated or various types of cottonseed oil in them.

The CHAIRMAN. Would not greater care be required?

Dr. Cox. We would think so. We have had not experience with cottonseed oil. We have had experience with certain types of hydrogenated peanut oil that are used in stabilizing peanut butter, and are already finding that some of these hydrogenated peanut oils have traces of benzene hexachloride. We have had to go back to the manufacturer and get after them and even give them analytical methods. And we have actually had to reject considerable amounts of hydrogenated peanut oil.

The CHAIRMAN. I think that is all, Dr. Cox. I want to join with the committee in expressing our thanks to you for your careful consideration of this subject. It has been most helpful, I know, to all of the

members who have had an opportunity to hear you and for the rest of the members who will read this record.

Have you another question, Mr. Kleinfeld?

Mr. KLEINFELD. Just one question. Do you buy peas for canning?

Dr. COX. We have two procedures. We have a considerable acreage in New York that is grown under contract, and then on occasion we run short of peas and we have to buy frozen peas from other areas.

Mr. KLEINFELD. Have you found DDT on your peas?

Dr. COX. We have not found DDT on processed peas because it does not penetrate into the pod.

Mr. KLEINFELD. Do you know whether DDT is used as an insecticide on peas?

Dr. COX. It has been used and we know in some cases where it still is.

Mr. KLEINFELD. Do you know what happens to the pea vines?

Dr. COX. In New York and in some of the Northern States it is made into silage and fed to dairy cattle.

Mr. KLEINFELD. A representative of the National Canners Association testified before this committee that the pea vine is sold for that purpose.

Now if DDT has been used and the pea vine is sold for fodder, that means that the cattle eating the pea vine will get DDT into their systems; is that right?

Dr. COX. That is true. We have considerable evidence to indicate that.

Mr. KLEINFELD. And DDT will accumulate in the cattle, will it not?

Dr. COX. From all the amount of evidence published it indicates that, yes.

Mr. KLEINFELD. Do you feel it is good sound practice for a canner to sell pea vines on which DDT is present for use as fodder for cattle?

Dr. COX. We have not felt that that was the case.

Mr. KLEINFELD. Do you think it is advisable to do that?

Dr. COX. We haven't done that.

The CHAIRMAN. Have you one more question, Mr. Horan?

Mr. HORAN. Off the record.

(Discussion off the record.)

Mr. KLEINFELD. Before calling the next witness, I have a letter from another canner, H. J. Heinz Co., which sets forth the general views of that company on the problems before this committee. It is a short letter and I suggest that it be made part of the record.

The CHAIRMAN. Did they request it?

Mr. KLEINFELD. They have agreed that it should be made a part of the record.

The CHAIRMAN. Unless we have objection?

Without objection, we will make it part of the record.

(The following letter was submitted for the record:)

H. J. HEINZ CO.,
Pittsburgh, Pa., November 8, 1950.

Mr. JAMES J. DELANEY,
House of Representatives, Washington, D. C.

DEAR MR. DELANEY: Your letter of October 18 in connection with the activities of your committee has been given careful consideration. The scope of the work

of your committee is so broad that it is not easy to cover the matter briefly or even within our own organization to investigate all the various considerations that can be brought up.

You state, however, that you are particularly interested in knowing what policy, if any, our company has followed with respect to the incorporation of chemicals in foods. We have a long history in this connection and, as it is a matter of record, there is hardly need to outline it in detail in this letter.

Our company was most active from 1900 to 1906 in assisting in the passage of the original Pure Food Act and worked very closely with Dr. Harvey Wiley in determining just what would be practical in that legislation. Previous to that time, chemical preservatives had been used to preserve food products and it was generally believed that spoilage and possible food poisoning might result if such chemicals were not used. Preservatives were grouped into two general classes: natural preservatives consisting of sugar, salt, vinegar, and spices; and artificial preservatives consisting of benozate of soda, salicylic acid, sulfur dioxide, etc. The matter was highly controversial and, according to our record, we became deeply involved in the discussions and it took a considerable amount of our time because we were one of the few in the industry who were willing to sponsor this movement on the part of Dr. Wiley to put the food industry on a better basis. Since that time we have not deviated from our policy of processing our food products without the use of chemical preservatives, but of being very particular about the ingredients we purchase to make sure they are free from such substances. Not only have we guarded against added chemicals but are constantly on the alert against accidental contamination from the type of metals we use in our utensils. Our finished products are regularly being checked for traces of copper, lead, zinc, etc., which might be picked up in the manufacturing process.

In the last few years the growing use of insecticides and pesticides has added to our burden. We realize that without their use it is very difficult to produce crops of the fruits and vegetables we need that are free of insect contamination. Insect contamination itself is very objectionable and we are constantly checking our products to be certain that it is kept to a minimum. We are, therefore, faced with a very definite problem. If we do not permit the use of chemicals on the crops to keep down the insect infestation, the finished product will be objectionable and, if we do permit the use of insecticides, the resulting product may be undesirable because of traces of these insecticides carried over into it. This is not a new problem. The use of lead arsenate sprays has gone back over the years and it is not possible to entirely remove these substances when preparing a product for consumption. Every possible effort has been made to do so and the Food and Drug Administration have arrived at certain maximums that are permissible, which are sometimes called tolerances. These are usually very small parts per million so that they are really just a trace. There is no argument about the toxicity of lead and arsenic because this is well recognized but it has seemed over the years that we have had to accept these minute traces. We are hopeful that some of the new insecticides will be just as efficient and much less toxic, but it will take considerable time to definitely establish these facts.

It is rather obvious that no substance should be used unless there are assurances that it will do no harm or that it can be entirely removed before consumption of the product. With definite poisons like arsenic and lead, agreement can be reached much faster than in the use of some of these new compounds about which not too much is known. Under certain conditions, table salt is a poison so the matter is not a simple one and will take much patience to work out.

If legislation can be drawn which will be practical to enforce and will take into consideration all the complexities of the problem, we would be in favor of such legislation being enacted. Certainly industry should fully express themselves on this matter in order to make such legislation feasible.

Yours very truly,

FRED HEINZ,
Special Assistant to the President.

The CHAIRMAN. Call the next witness.

Mr. KLEINFELD. Dr. Hines.

The CHAIRMAN. Your name and address, Doctor.

Dr. HINES. Don Carlos Hines, Conarroe Road, New Augusta, Marion County, Ind.

(The oath was administered by the chairman.)

TESTIMONY OF DON CARLOS HINES, M. D., NEW AUGUSTA, IND.

Mr. GOTTLIEB. Are you a medical doctor, sir?

Dr. HINES. Yes.

Mr. GOTTLIEB. Are you an endocrinologist?

Dr. HINES. Yes.

Mr. GOTTLIEB. Have you contributed papers to the scientific literature?

Dr. HINES. A few.

Mr. GOTTLIEB. About how many, would you say?

Dr. HINES. Maybe two or three.

Mr. GOTTLIEB. Have any of these been on diethylstilbestrol?

Dr. HINES. No.

Mr. GOTTLIEB. Whom are you representing here today, sir?

Dr. HINES. I don't think I can say that I am representing anyone but myself. I am associated with Eli Lilly & Co., but no one in that organization has seen the contents of my statement, nor have I discussed it with anybody.

Mr. GOTTLIEB. Did Eli Lilly & Co. request that you testify here today?

Dr. HINES. That is right.

Mr. GOTTLIEB. Did the Wick & Fry Co., Inc., request that you testify here today?

Dr. HINES. That is right.

Mr. GOTTLIEB. What does the Wick & Fry Co. manufacture?

Dr. HINES. I don't know very much about Wick & Fry.

Mr. GOTTLIEB. What does Wick & Fry manufacture in the diethylstilbestrol line?

Dr. HINES. I understand they manufacture pellets for implantation in chickens.

Mr. GOTTLIEB. You understand they manufacture diethylstilbestrol pellets for implantation in chickens?

Dr. HINES. Right.

Mr. GOTTLIEB. And does Eli Lilly manufacture diethylstilbestrol?

Dr. HINES. They do.

Mr. GOTTLIEB. Do they sell the diethylstilbestrol to the Wick & Fry Co.?

Dr. HINES. I understand that they do.

Mr. GOTTLIEB. Is that the only connection between Eli Lilly and Wick & Fry, to your knowledge?

Dr. HINES. Yes.

Mr. GOTTLIEB. Who is Dr. Edward Campbell?

Dr. HINES. Well, until recently he was director of the division of biological chemistry in Eli Lilly & Co. Very recently he retired. I understand he has a connection with Wick & Fry.

Mr. GOTTLIER. And when he was employed by Eli Lilly he was also employed by Wick & Fry; was he not?

Dr. HINES. I don't think he was employed by them.

Mr. GOTTLIEB. Was he an official of that company?

Dr. HINES. I think so.

Mr. GOTTLIEB. He was vice president of Wick & Fry while he was employed by Eli Lilly, was he not?

Dr. HINES. He may have been; I don't know.

Mr. GOTTLIEB. Is Mr. Harry Wick an official of the Wick & Fry Co.?

Dr. HINES. I believe so.

Mr. GOTTLIEB. Do you know whether he is employed by Eli Lilly?

Dr. HINES. He definitely is.

Mr. GOTTLIEB. He is?

Dr. HINES. Yes.

Mr. GOTTLIEB. In what capacity?

Dr. HINES. Again I couldn't tell you his exact title.

Mr. GOTTLIEB. Generally.

Dr. HINES. But he has to do with animal assays.

Mr. GOTTLIEB. Are you employed by Wick & Fry in any capacity?

Dr. HINES. No.

Mr. GOTTLIEB. Your experience with diethylstilbestrol has been essentially with clinical use; is that correct?

Dr. HINES. Yes.

Mr. GOTTLIEB. Will you read your statement, Doctor.

Dr. HINES. My name is Don Carlos Hines. I reside in Marion County, Ind., in the suburbs of Indianapolis. I was born in San Jose, Calif., in 1904. After the usual preliminary schooling, I received the M. D. degree from the Stanford University School of Medicine in 1930. This was followed by 2 years of training as assistant resident physician in medicine and 1 year as resident physician in medicine at the Stanford University Hospitals, San Francisco. From 1933 to 1934 I was chief of the medical out-patient clinic at the same institution. From 1934 to 1939 I was in the private practice of internal medicine in Palo Alto, Calif., spending 1 day a week teaching at the Stanford Medical School. I am certified as a specialist in internal medicine by the American board of that specialty.

In 1939 I joined the research staff of the pharmaceutical manufacturers, Eli Lilly & Co., of Indianapolis. As a member of the medical department, I have had charge of the clinical program with estrogens, the group of compounds that includes diethylstilbestrol. Early in 1940, when diethylstilbestrol was under clinical investigation, the Food and Drug Administration requested those pharmaceutical manufacturers who were interested in the drug to pool the results of their investigation for presentation to the Administration as a unit. I acted as chairman of the committee which managed this enterprise. I prepared the questionnaires which went out to investigators. The data were submitted to me for analysis and summarization. The product literature which I wrote was chosen by the Food and Drug Administration as a model for all companies to follow.

We submitted to the Food and Drug Administration reports covering more than 8,000 patients who had received the new drug. Eighteen hundred of these patients had received it more or less continuously over periods ranging from 6 months to 2 years. Diethylstilbestrol was finally marketed in September 1941, after the most thorough investigation that any new drug had received up to that time. During the years since then, it has had very wide use.

During the past 12 years a large part of my interest has centered on the various effects of diethylstilbestrol on human beings. During that period I have used the drug clinically myself, I have read almost everything that has been published in English concerning it, and

I have discussed it personally with a very large number of investigators and practicing physicians.

NATURE, ACTION, AND USE OF DIETHYLSTILBESTROL

In the animal and human body, diethylstilbestrol has the actions of an estrogen. Substances of this type are sometimes called female sex hormones because among their properties is that of causing development of the female accessory genital organs. However, the estrogens have other properties as well, and as Dr. Robert Greenblatt stated before this committee, they occur normally in men as well as in women.[1] In fact, as Dr. Byerly and Dr. Greenblatt both have previously told you, they are found in minute quantities in a great many substances, including foods.[2 3] Diethylstilbestrol has all the physiological effects of the estrogens produced by human and animal ovaries, even though it differs from them chemically.

Estrogens have a number of uses in medicine. They are given to control the symptoms associated with the menopause (or change of life) in women, they are useful in certain types of inflammations of the female genital tract, and they have value in certain types of disturbance of menstruation. They are also useful to prevent or relieve the painful engorgement of the breasts which may occur following childbirth. They are used extensively for symptomatic control of cancer of the prostate gland in men and advanced cancer of the breast in women. To avoid misunderstanding, I should say here that estrogens do not cure any cancers, but they may hold certain forms of the disease in abeyance for considerable periods of time.

Among the estrogens that are available for clinical use, diethylstilbestrol is one of the most important. The estimates regarding the total sale of diethylstilbestrol in the United States, as made by the United States Tariff Commission, are as follows: In 1946, 500 pounds [4]; in 1949, 1,100 pounds [5]; and in 1950, 2,700 pounds.[6] Some of this increase is undoubtedly due to the treatment of poultry, but not all, because our own market research indicates that the use of diethylstilbestrol for human therapy has been steadily increasing over the past few years.

FALLACY OF ATTEMPTING TO APPLY RESULTS OF ANIMAL EXPERIMENTS DIRECTLY TO MAN

It should be pointed out that different species of animals may have very different responses to the same sex hormones. For instance, a substance that stimulates lactation, that is, milk production, in one species may tend to inhibit it in another. One is seldom justified in carrying over observations from one species to another. This includes the carrying over to human beings of observations made on experimental animals. In fact, I cannot overemphasize the fallacies inherent in efforts to apply directly to man the results of animal experiments in the field of the hormones.

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[1] Committee hearings, pt. I, 1951, p. 458.
[2] Committee hearings, pt. I, 1951, p. 419.
[3] Committee hearings, pt. I, 1951, p. 462.
[4] U. S. Tariff Commission Report No. 159, table 14A, p. 34.
[5] U. S. Tariff Commission Report No. 169, table 17A, p. 31.
[6] U. S. Tariff Commission Report No. 173, table 17A, p. 32.

The effects of diethylstilbestrol on human beings depend to a certain extent on the sex, age, and condition of the individual consuming it and also to a very important degree on the amount consumed and the duration and constancy of this consumption. The constancy of consumption is important because diethylstilbestrol persists in the human body only a short time. Single doses of the order of 12 to 15 milligrams seem to be completely destroyed or excreted in 3 or 4 days.[7] [8] Larger doses probably require a little longer. If consumption is intermittent, the body escapes periodically from the influence of the drug. I shall discuss this point again later.

The "Canadian experiment": In connection with the eating of chickens which have been treated with diethylstilbestrol pellets, there are, of course, two possibilities for the consumption of diethylstilbestrol itself. One is in the tissues of the chicken, and the other is through accidental eating of a pellet that may not have been completely absorbed. With regard to the amount of estrogen that would be consumed in the meat and organs of treated chickens, there has been considerable discussion before this committee of a publication by Bird, Pugsley, and Klotz.[9] These investigators administered estrogens to chickens and subsequently assayed the tissues in special ways. A number of estrogens were employed. I shall pick out two for comment, one because its action has previously been discussed before this committee, the other because it is the estrogen which is actually under consideration by this committee. These two are the dimethyl ether of diethylstilbestrol and diethylstilbestrol itself. The chemical relationship between them is very much like that between the ether which is used for anesthesia and ordinary grain alcohol. One does not have to be scientifically trained to know that these last two have somewhat different properties.

However, in the case of diethylstilbestrol and its dimethl ether, there are the same qualitative effects; but the chemical difference makes them act very differently in a quantitative way. Several aspects of this difference are demonstrated by the experiments of Bird and coworkers. For one thing, diethylstilbestrol was more potent when injected under the skin of rats than when given by mouth. This is the usual experience with drugs. In contrast, the dimethyl ether of diethylstilbestrol was more potent when taken by mouth than when injected. This very important contrast in behavior can only be due to a profound difference in the way in which the two substances are metabolized in the body.

I am informed that the pellets marketed by Wick & Fry, Inc., weigh about 15 milligrams, but that only about 12 milligrams is diethylstilbestrol; the rest is a binder which holds the pellet together. It has been testified before this committee that a 15-milligram pellet which is implanted under the skin is absorbed in about 6 weeks, providing an average daily uptake of a little more than 0.3 milligrams.[10] Bird and coworkers fed the dimethyl either of diethylstilbestrol to

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[7] Mazer, C., Israel, S. L., and Ravetz, E.: The Synthetic Estrogen Stilbestrol: An Experimental and Clinical Evaluation, J. A. M. A., *116*: 675, 1941.

[8] Von Haam, E., Hammel, M. A., Rardin, T. E., and Schoene, R. H.: Clinical Studies on Stilbestrol, J. A. M. A., *115*: 2266, 1940.

[9] Bird, S., Pugsley, L. I., and Klotz, M. O.: The Quantitative Recovery of Synthetic Estrogens From Tissues of Birds (Gallus Domesticus), the Response of the Birds' Testis, Comb, and Epidermis to Estrogen and of Humans to Ingestion of Tissues From Treated Birds, Endocrinology, *41*: 282, 1947.

[10] Committee hearings, pt. I, 1951, p. 459.

chickens at the rate of 13.2 to 20 milligrams per day, to total dosages of 156 to 242 milligrams in 12 days. Naturally, they found considerable quantities of estrogen in the livers and fat of these chickens, and these livers and this fat had some hormonal effect when fed to postmenopausal women. I say "naturally" because of the following chain of circumstances. As has been pointed out by previous witnesses before this committee, only a relatively small part of administering estrogen is excreted in either animals or human beings. Most of it is destroyed in the body, and the principal site of destruction seems to be the liver. But the destruction of many chemical substances, both in the test tube and in the animal and human body, is greatly impeded if their free hydroxyl groups are protected by the formation of methyl ethers. This is just the situation with the dimethyl either of diethylstilbestrol, and it explains the observed fact that this substance is very slowly destroyed and eliminated and consequently has a very prolonged action.

It has also been observed that certain substances which are soluble in fat—DDT has been mentioned this morning—(as are both diethylstilbestrol and its dimethyl ether), when they appear in the body faster than they can be destroyed, are stored temporarily in the body fat. Since the destruction of the dimethyl ether of diethylstilbestrol is a much slower process than the destruction of diethylstilbestrol, it is not at all surprising that the dimethyl ether should have a more prolonged action than diethylstilbestrol and should be present in high concentrations in the liver and body fat of treated animals, especially after administration of such extremely large doses. It would, therefore, be unwise to permit the sale of chickens that had been given quantities of 13 to 20 milligrams of the dimethyl ether or diethylstilbestrol daily in their food for a period of as long as 12 days.

Dr. MILLER. In that connection, if I may ask this, sir?

Dr. HINES. Yes.

Dr. MILLER. What is your opinion about the pellets used on chickens in the smaller dosages which they inject under their neck? You were talking about the larger doses here.

Dr. HINES. I was talking about the dimethyl ether of diethylstilbestrol, which is a different substance.

Dr. MILLER. What?

Dr. HINES. Dimethyl ether of diethylstilbestrol, and that is a different substance.

Now, then, the reason I mention this at all is that it was apparently upon the assumption that diethylstilbestrol was equivalent to its dimethyl ether that Dr. Enders based his testimony before the committee, and actually the chickens aren't being treated with the dimethyl ether.

I do not know of any chickens that are being marketed in this country after treatment with the dimethyl ether of diethylstilbestrol. The procedure we are discussing is the deposition of one pellet containing 12 milligrams of diethylstilbestrol itself in the neck of chickens, yielding an average absorption of about 0.3 milligram per day (or, in the case case of two pellets, about 0.6 milligram).

Let us return to the experiments of Bird, Pugsley, and Klotz with diethylstilbestrol itself. They did not implant pellets yielding an average absorption of 0.3 milligram per day. They injected 2 milligrams daily as an oil solution for 5 days. This treatment represents

six times the dosage rate provided by a single pellet, and three times the dosage rate provided by two pellets. Diethylstilbestrol is rapidly absorbed from an oil solution. Because of its rapid destruction, an equilibrium can be expected to have been reached by the end of the 5-day period of treatment, so that the accumulation of the drug in the animal would not increase with a longer period of treatment.

What did Bird and his coworkers find? Whereas the dimethyl ether of diethylstilbestrol had accumulated in the body fat to the extent of 1.5 to 4.7 milligrams per 100 Gm. of tissue, when diethylstilbestrol itself was given, even in doses six times those provided by a pellet the accumulation was too small to measure. The investigators say: "* * * in the case of * * * diethylstilbestrol it was impossible to obtain any quantitative estimation of the amount present," and in the accompanying table (table 3) the amount is listed as zero.[11] In this connection you will recall the finding of Bird and coworkers that diethylstilbestrol is more potent when injected than when administered orally.

I can find no reference in Bird's article to any assay of the livers of chickens treated with diethylstilbestrol itself, nor was either the liver or the fat of such chickens employed in human experiments.

The observations of Bird, Pugsley, and Klotz therefore provide absolutely no evidence that the treatment of chickens with diethylstilbestrol pellets makes the flesh dangerous for human consumption. Any such interpretation is entirely gratuitous and is totally unsupported by the facts.

Dr. MILLER. At that point, let me ask another question:

We have a bill before Congress, and it may pass, in which the mink growers are demanding damages from the United States Government because they fed the heads of these chickens, and entrails of these chickens, as suggested by the Agriculture Department, to the mink. Now the mink are sterile. The bill is on the calendar. It was objected to just recently. I take it, then, from your testimony that these mink growers are absolutely out, having nothing to stand on, that the feeding of the heads of chickens to the mink had no effect upon them at all.

Dr. HINES. No.

Mr. JONES. He didn't say that.

Dr. HINES. There is nothing in my testimony that would suggest that at all. I am talking about the effects on humans.

Dr. MILLER. You don't think it would have the same effect as on mink?

Dr. HINES. Not necessarily.

Dr. MILLER. You don't think the mink were made sterile because they were fed heads of chickens that were fed these pellets?

Dr. HINES. I have no knowledge of that of my own information. If that has been the observation, I would not question it.

Dr. MILLER. But you think the effects on the mink would not happen on humans?

Dr. HINES. No, I don't think that one can draw any conclusion as to humans from what happens to mink. I am basing what I have to say entirely on the work that has been done by other people.

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[11] Bird et al., supra, note 9, at 285.

Dr. MILLER. I know, but you are making an observation here from Bird, Pugsley, and Klotz that there is absolutely no evidence—and that is underlined—that the treatment of chickens with these pellets makes their flesh dangerous for human consumption.

Dr. HINES. Well, sir, I have here a reprint of Bird's article, and if you want to look at that——

Dr. MILLER. I have seen it.

Dr. HINES. And right here in table 3, in the line that says "diethylstilbestrol, subcutaneous administration, adipose tissues, milligrams per hundred grams of estrogen," the figure is zero.

Dr. MILLER. All right, go ahead.

Dr. HINES. How can a zero quantity of estrogen harm anybody? I am talking about the amount of estrogen in the adipose tissue. I am not talking about the eating of the residues of pellets themselves. Right now I am discussing what is in the tissues of the birds.

Dr. MILLER. Do you include the liver?

Dr. HINES. Well, Bird and his coworkers didn't assay the livers of those treated with diethylstilbestrol; they assayed the livers of birds treated with dimethyl ether but not diethylstilbestrol itself.

Dr. MILLER. Do you think there would be anything wrong in eating the necks of chickens that had these pellets put into them?

Dr. HINES. That is something I cover.

Dr. MILLER. That is what the committee would like to know. Do you have that in your paper?

Dr. HINES. Yes, definitely.

Dr. MILLER. Fine—go right ahead.

Dr. HINES. I would like to make clear what I am talking about now is Bird, Pugsley, and Klotz' study, because that has been quoted as providing evidence that the flesh and livers of these chickens treated with the pellets would be dangerous for consumption—and what I am pointing out is that if one can come to any conclusion from the paper of Bird, Pugsley, and Klotz, there is no estrogen in the tissues. That is what they found.

Dr. MILLER. Let me see the paper, will you, please?

Dr. HINES. Yes [passing document].

The CHAIRMAN. Go ahead.

Dr. HINES. I might say here that Bird, Pugsley, and Klotz used rats as their assay animals, and rats aren't nearly as sensitive as mice. You can detect with mice about one-tenth the quantity of estrogen that you can detect using rats.

ASSAYS OF TISSUES OF DIETHYLSTILBESTROL-TREATED CHICKENS

However, there is other evidence available. By techniques that are more sensitive than those employed by Bird and coworkers, qualified investigators of two different laboratories have assayed the livers and carcasses of diethylstilbestrol-implanted chickens and also two beef livers bought from a reputable meat packer. Reports of these assays are attached to my prepared statement, for the information of the committee, as appendixes A and B, and I have here signed copies for the files of the committee.

One of the laboratory men is Dr. Roland K. Meyer, of the University of Wisconsin. Dr. Meyer's qualifications are stated in appendix A. The other is Dr. E. D. Campbell, who made the assay reported in

appendix B. Dr. Campbell's qualifications are also set forth in appendix B. Both men are experts in their fields. And Dr. Meyer, of course, has no connection with either Wick & Frye or Eli Lilly & Co.

I wish to discuss the two beef livers involved in the assays. They had been passed as fit for human consumption by a United States Government inspector. Both livers were from pregnant cows; and, if they had not been purchased for analysis, they would undoubtedly have been sold by a butcher to grace family dinner tables. I have not seen the results of any assays of nonpregnant beef livers, and I suspect that the estrogen content might be lower in them. The point, however, is that it seems to be accepted practice to employ the livers of pregnant cattle as food, so that these livers do not represent an unusual article of diet. Insofar as I know, no one has ever suggested that beef liver was in any way a harmful article of diet except in gout, and then not because of its estrogen content.

According to the assays of Meyer and Campbell, one of the livers contained the equivalent of 0.026 microgram of estrone per gram of liver; the other contained the equivalent of about 0.35 microgram of estrone per gram. Thus, one liver contained more than 10 times as much estrogen as the other. These results illustrate the variations that must be expected when different specimens are assayed in different laboratories. However, despite the variations, these determinations have value. If we calculate the amount of beef liver that would be required to provide an average daily therapeutic dose of estrogen for treatment of menopausal symptoms, we arrive at the figures 7 pounds and 83 pounds, respectively, on the basis of these two assays.

It is of interest that the livers of treated chickens were found by both laboratories to contain less estrogen than those of the two beeves. The carcasses of treated chickens contained still less estrogen; in fact, one laboratory could find none at all, or, at least, an immeasurably small quantity.

The CHAIRMAN. That is something new, Doctor. That is something I do not think anyone has given a great deal of thought to?

Dr. HINES. You mean the estrogen?

The CHAIRMAN. Of, say, pregnant cows sold on the market.

Dr. HINES. Well, these are facts.

The CHAIRMAN. We don't question that. But I say no great amount of thought has been given to that in the past.

Dr. HINES. No one has considered that beef liver was made unsuitable for human consumption by that.

The CHAIRMAN. No.

Dr. HINES. The point I am making is that people have been eating livers and tissue of animals right along.

Over a period of time, people tend to eat just enough to keep up their supply of energy. If they do not take one kind of food, they will take another. If they eat chicken, then, they eat it in place of some other food which they would have eaten if the chicken had not been available. We have all obviously been eating estrogen in our food for many generations. I grant that it is impossible to say exactly how much we eat, but whatever quantity it is must be considered physiological rather than pathological. The range is undoubtedly rather wide. I can see no possibility of harm resulting from substitution of the flesh or the livers of treated chickens for some other food which

may contain no estrogen at all or may contain, like those beef livers, even more estrogen than the chicken. It all falls in the range that must, in view of the experience of the human race, be considered physiological, that is, normal. As I understand Dr. Greenblatt's testimony, he is of a like opinion.

Before leaving this subject, I wish to add one comment on the biological assay of estrogens. All methods have limits to their accuracy, and their interpretation has pitfalls. However, I think it can be said that any systematic errors inherent in a particular method will be reflected in all assays performed by that method in a given laboratory. Therefore, if an established method in the hands of an experienced technician shows that beef liver contains more estrogen than the livers of stilbestrol-treated chickens, that difference can be accepted as valid, regardless of whether the absolute quantities may be correct.

ACCIDENTAL INGESTION OF AN INCOMPLETELY ABSORBED PELLET

I now turn to consider the effects that might be produced by eating an incompletely absorbed pellet, or a number of such pellets. If the necks of treated chickens are made into soup, the remains of the pellets will be boiled and may stay in the tissues of the neck or may be freed. It is my understanding that the binder which holds the Wick & Fry pellet together—I have no detailed information on other pellets—will disintegrate in boiling water, thus liberating the crystals of the drug. The United States Pharmacopeia, fourteenth revision, states that diethylstilbestrol is almost insoluble in water. It may be presumed, therefore, that the drug will either remain in the neck as a mass of crystals or will appear as a white sediment in the bottom of the vessel.

Let us assume that there is some chance that one or a number of pellets or their contents may be eaten and absorbed, not once but at intervals of a few days. What can be expected to happen? Diethylstilbestrol has been used in medicine to a sufficient extent and over a long enough period of time so that one can answer such a question in terms of actual experience in human beings, and not by some analogy to experimental animals which may have no validity for man.

Children: Before the advent of the sulfonamides and antibiotics, the administration of diethylstilbestrol was considered a very satisfactory treatment for the form of gonorrhea innocently contracted sometimes by little girls. The principal medical publications on this subject were by Woodruff and TeLinde [12] of the Johns Hopkins Hospital of Baltimore and Russ, Collins, and Powell [13] of the Tulane University School of Medicine in New Orleans. The dosage usually employed was 3 milligrams of diethylstilbestrol daily by mouth until a total quantity of 20 milligrams had been taken. Russ, Collins, and Powell treated 124 cases by this method. They reported that all of the little girls developed swollen and pigmented nipples during the period of administration. Perhaps 20 percent had other temporary changes in the secondary sex organs. A few had nausea and vomiting. The authors say:

> No patient was observed in whom toxic or unpleasant symptoms arising from the drug warranted its discontinuance. True, certain side effects were

[12] Woodruff, J. D., and TeLinde, R. W.: The Treatment of Gonococcal Vaginitis in Children With Diethylstilbestrol, South. M. J., 35: 389, 1942.
[13] Russ, J. D., Collins, C. G., and Powell, S.: Treatment of Prepuberal Vulvovaginitis With Diethylstilbestrol, J. Clin. Endrocrinol., 2: 383, 1942.

observed * * * but none was more than mild in nature and all regressed completely within 2 weeks following completion of therapy * * * No permanent change was observed in any patient, nor was any symptom observed that would make us hesitate to apply this form of therapy in any case of infant vaginitis.

Woodruff and TeLinde treated 21 cases. They observed similar side effects, but they state:

For the most part, these effects were transient and we have no direct evidence that any of them are harmful.

From our knowledge of the action of diethylstilbestrol, it can be said definitely that if the 20 milligrams had been given in a single dose rather than over a period of 1 week there would have been a higher incidence of vomiting and a very much lower incidence of effects on the sexual organs.

These quotations can be verified, of course, from the references appended to my statement.

Adult women: Diethylstilbestrol has been given——

Dr. MILLER. Before you get to that, I notice on the question of children you speak about not having any harmful effects, but you do say these men reported that all of the little girls developed swollen and pigmented nipples during the period of administration, and perhaps 20 percent had other temporary changes in the secondary sex organs; a few had nausea and vomiting.

Dr. HINES. Yes.

Dr. MILLER. That might indicate there was something in the drug that would be harmful to children.

Dr. HINES. Well, these are the same changes that normally take place during adolescence. I don't think anybody regards that as harmful. Also, the same changes are sometimes seen in new-born babies from the estrogen they have absorbed through the placenta from their mothers. Sometimes new-born infants will have a drop or two of milk from their breasts. That is the same kind of effect, and that goes away and is not considered to be harmful.

Dr. MILLER. Would you say it would be helpful to the youngster to give it?

Dr. HINES. Not helpful.

Dr. MILLER. Just sort of neutral, neither good nor bad; probably all right if you want to use it. It might be good and it might be bad.

Dr. HINES. I wouldn't say it might be good and it might be bad; I would say it isn't either good or bad, which is a little bit different.

Dr. MILLER. All right.

Dr. HINES. Mind you, this is when 20 milligrams were given in the course of a week. Now, that represents more than is in one pellet. At the end of 6 weeks, as I understand it, the pellets usually have one or two milligrams, so that would mean the remains of 10 or 20 pellets that had been in 6 weeks.

Mr. HORAN. That is in the patient being treated for gonorrhea?

Dr. HINES. Yes. So, you see this represents an amount that I think a child is unlikely to get. But what I am reporting is what the effects are, what we know about the effects of stilbestrol on people; and, then the application of that to the chicken pellets, that is a matter for the committee, but if the chickens have been slaughtered, at the end of 6 weeks this would represent the remains of anywhere from 10 to 20 pellets that would be required to do that, taken over the course of a week.

Adult women: Diethylstilbestrol has been given to adult women in large doses for treatment of functional uterine bleeding, a condition in which bleeding occurs at unexpected times or in unexpected quantity in the absence of structural changes in the uterus. It is thought to be due to a disturbance in endocrine balance. A number of medical publications have dealt with this subject.[14 15 16 17 18 19 20 21] Palmer gave diethylstilbestrol to some patients in the amount of 15 milligrams per day for 2 or 3 days and to others in the amount of 42 milligrams over a 2-week period.[22 23] He reports no permanent or definitely harmful effects. He stresses the observation that it is only continuous therapy that produces harmful effects. The other investigators whose work is listed in my bibliography used amounts of diethylstilbestrol at least as large as those given by Palmer. None of them mentions any side effects or undesirable results from the treatment. In fact, the function of the ovaries of most of the patients was better after the treatment than before. Of course, these women had disturbances of ovarian function.

The question may be raised as to the effect of diethylstilbestrol on completely normal women. The most that could be expected from single doses of 10 to 30 milligrams or even more would be some temporary and harmless menstrual irregularity which would not occur in every instance.

(Discussion off the record.)

The CHAIRMAN. We will recess until 2 o'clock.

(Whereupon, at 12:30 p. m., a recess was taken until 2 p. m. of the same day.)

AFTERNOON SESSION

Mr. JONES (presiding). The committee will come to order, please, and we will continue with Dr. Hines.

Dr. Hines, you may continue.

TESTIMONY OF DON CARLOS HINES, M. D.—Resumed

Dr. HINES. I think there are some things, perhaps, that maybe we had better clear up before I go on.

Questions were asked about the effect of stilbestrol on the mink, and, of course, I do not know anything directly about that, but I would point out that presumably the minks got residues of many, many pellets, since I understand they were fed—their diet was exclusively, if not practically exclusively, the heads of the treated chickens; the mink—I do not know exactly what it weighs—but it certainly is many times smaller than a human being.

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[14] Palmer, A.: Clinical Experiments With Diethylstilbestrol, Estrogen Withdrawal Bleeding in Primary and Postmenopausal Amenorrheic Women, Am. J. Obst. & Gynec., *41*: 861, 1941.

[15] Palmer, A.: Clinical Experiments With Diethylstilbestrol. II. The Treatment of Uterine Bleeding, Am. J. Obst. & Gynec., *41*: 1018, 1941.

[16] Palmer, A.: Cyclical Estrogen Therapy, Am. J. Obst. & Gynec., *44*: 56, 1942.

[17] Karnaky, K. J.: Cause of Menstruation and Uterine Bleeding, South. M. J., *33*: 1285, 1940.

[18] Karnaky, K. J.: Discussion of Paper by Randall et al., Am. J. Obst. & Gynec., *43*: 385, 1942.

[19] Cuyler, W. K., Hamblen, E. C., and Davis, C. D.: Diethystilbestrol for Hemostasis in Functional Uterine Hemorrhage, J. Clin. Endocrinol., *2*: 438, 1942.

[20] McGinn, E. J.: Functional Uterine Bleeding, J. Clin. Endocrinol., *2*: 302, 1942.

[21] Davis, M. E.: Functional Uterine Bleeding, M. Clin. North America, *31*: 223, 1947.

[22] Palmer, A., supra, note 15.

[23] Palmer, A., supra, note 16.

In addition to that, one certainly cannot draw any conclusions from the mink regarding any other kind of animal, including human.

Now, the mink may react in the same way as other animals, I do not know; one has no assurance of that.

Mr. HORAN. May I ask you a question on that? I want you to understand it is not facetious, but the mink has been famous as being very prolific, and I think that might have some basis of conjecture, at least, on the part of a lay mind that any additional—what do you call this——

Mr. KLEINFELD. Stilbestrol.

Mr. HORAN (continuing). Stilbestrol might unbalance the constitution of that sort of animal life to the point where it could be affected. That is a possible conjecture, is it not?

Dr. HINES. I do not question an observation that the mink were rendered sterile. I mean, that is outside my observation; but if competent people say it is so, I am prepared to believe it.

But my point is that, first, the minks presumably got tremendous doses, and, in the second place, that they are very much smaller animals, so that the dose is distributed in a smaller bulk of tissue, and then, in the third place, what applies to the mink in any case does not necessarily apply to the human.

Now, we have some evidence, I think, which I will present here on the posible effect of stilbestrol on fertility in human beings. I think there is some positive evidence there.

Another thing I wanted to emphasize is the importance of the distinction between continuous treatment and intermittent treatment. An individual who is subjected continuously day after day to an estrogen like diethylstilbestrol can be expected to have very different effects from one who gets, perhaps, the same total dose, but gets it intermittently, with intervals of no administration, because, as has been pointed out several times, diethylstilbestrol itself is very rapidly eliminated from the body, so its effects do not persist more than just a very few days.

I would also like to comment that the connection of Dr. Edward Campbell and Mr. Wick with both Wick and Frey and Eli Lilly & Co. was pointed out in appendix B here, which gives the results of assays of beef liver and chicken carcasses.

Just before the intermission, we discussed the effect of diethylstilbestrol on women with functional uterine bleeding, and pointed out that these treatments given sometimes over a 2-week period were not followed by any harmful effects.

Now then, that brings up the question of the effect of diethylstilbestrol on completely normal women, and single doses because of their rapid excretion (and this applies no matter how large they are), would have very much less effect. So that I would say that from what we know about the subject, the most that you could expect from single doses would be that in a few instances there might be some delay or early arrival of the menstrual period which would hold for that period only; and that, of course, is not in any way harmful.

As a matter of fact, in studies that have been made where the periodicity was carefully recorded, it has been found that very few women are absolutely regular.

Now, diethylstilbestrol has also been given for prevention of various accidents of pregnancy, such as abortion. Some concern has been ex-

pressed before this committee on the possibility that diethylstilbestrol ingested accidentally in the form of pellets or even that quantity which is in the flesh of treated chickens might induce abortions in pregnant women. It is true that in certain species of animals large doses of estrogens, including diethylstilbestrol, may cause abortion or, in the absence of abortion, may cause severe damage to the fetuses. This is another of those instances of great difference in the reaction of different species. On the basis of presumed analogy with certain experimental animals, two different investigators attempted to produce therapeutic abortion with diethylstilbestrol in large doses.[24] [25] Both were completely unsuccessful. More recently diethylstilbestrol is being employed for the prevention of abortion.[26] [27]

Smith & Smith [28] of Boston have studied the effects of diethylstilbestrol on pregnancy. They gave the drug to 387 women who were undergoing their first pregnancy. As you know, the average pregnancy lasts 40 weeks. Administration of the drug was begun before the twentieth week and was continued through the thirty-fifth week of pregnancy. When treatment was begun as early as the twelfth week, diethylstilbestrol was given by mouth in a dosage of 12.5 milligrams daily. This was gradually increased until in the twentieth week the daily dose was 50 milligrams, in the thirtieth week, 100 milligrams, and in the thirty-fifth week, 125 milligrams (in some instances, 137.5 milligrams). May I emphasize that these are daily dosages. The authors state:

> With the exception of an occasional complaint of nausea or itching of the skin, no toxic effect could be attributed to the stilbestrol—diethylstilbestrol—as administered. In no instance was the drug discontinued or the dosage changed because of symptoms, despite which fact the symptoms disappeared. There were no deaths among the treated or control mothers of this study.

The above statement, based, as it is, on a series of 387 treated cases, establishes beyond doubt the harmless nature of even very large quantities of diethylstilbestrol taken continuously through most of pregnancy. Although it is incidental to the present discussion, it may be of interest to note that in the treated group, as compared with an untreated but otherwise similar control group of 555 women pregnant for the first time, there was a lower incidence of toxemia of pregnancy and of infant deaths and a greater average size and weight of the babies born alive. In other words, these large doses did not harm the babies.

Adolescent boys and girls: For a number of years diethylstilbestrol has been employed in the treatment of acne vulgaris, the disease which causes pimples and similar unsightly outbreaks on the faces and necks of adolescent boys and girls. Lawrence and Werthessen of Tufts College Medical School in Boston have published what is perhaps the most detailed study.[29] These authors treated 20 patients

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[24] Abarbanel, A. R.: The Priming Action of Stilbestrol on the Gravid Human Uterus, Surg., Gynec. & Obst., *73*: 257, 1941.

[25] Zondek, B., and Bromberg, Y. M.: Autodetoxication of Stilbestrol During Pregnancy, Lancet, *1*:381, 1942.

[26] Abarbanel, A. R.: Discussion of Paper, Female Infertility, by G. H. Gardner, J. A. M. A., *128*: 248, 1945.

[27] Rosenblum, G., and Melinkoff, E.: Preservation of the Threatened Pregnancy With Particular Reference to the Use of Diethylstilbestrol, West. J. Surg., *55*: 597, 1947.

[28] Smith, O. W., and Smith, G. V. S.: The Influence of Diethylstilbestrol on the Progress and Outcome of Pregnancy as Based on a Comparison of Treated With Untreated Primigravidas, Am. J. Obst. & Gynec., *58*: 994, 1949.

[29] Lawrence, C. H., and Werthessen, N. T.: Treatment of Acne With Orally Administered Estrogens, J. Clin. Endocrinol., *2*: 636, 1942.

with diethylstilbestrol and 5 with a synthetic estrogen related chemically to the natural ones. In the complete group, there were 14 females and 11 males. The dosage of diethylstilbestrol varied from 0.5 to 2 milligrams daily. It was continued for 2 to at least 9 months. In the men administration was continuous, whereas in the women the drug was omitted 4 days before the due date of menstruation and was resumed only after menstruation had ceased. Concerning side effects, the authors say:

> In two males slight gynecomastia—[and I may interpolate by saying that is enlargement of the breasts]—and in one, pigmentation of the nipples, appeared, but receded rapidly when treatment was omitted in the two who have remained under observation. This reaction suggests that it may be wise to employ intermittent treatment in males as well as females.

Now, again, I comment that it was men who had continuous administration over a number of months.

It will be noted that in these young men and women (average age of men, 20 years; of women, 25.8 years) even prolonged administration of diethylstilbestrol in doses of 0.5 to 2 milligrams daily produced no observable effects beyond the period of administration. Administration of the same total weekly quantity, that is 3.5 to 14 milligrams, in a single dose once a week would have even less tendency to produce lasting effects than the daily administration employed by Lawrence and Werthessen.

Andrews, Domonkos, and Post[30] report very favorably on several hundred patients given diethylstilbestrol by mouth for acne. The average dosage was 0.25 milligram daily, and the extremes were 0.1 and 0.5 milligram. Menstrual irregularities were noted in 25 percent of the 262 female patients, but these were abolished by intermittent administration. They call particular attention to one man who received 0.5 milligram daily for 4 months. During this period his wife became pregnant and was later delivered of a 9-pound boy.

Men: Two reports are available concerning administration of diethylstilbestrol in prevention and treatment of the orchitis (inflammation of the testicles) which may occur in men as a complication of mumps.[31] [32]

Savran treated 77 soldiers, giving 4 milligrams daily for 7 days (a total of 28 mg.). Hoyne and coworkers treated 64 patients, some with 1 milligram daily, some with 2 milligrams daily, and some with 5 milligrams daily for unstated periods. In both series the incidence and severity of orchitis were materially reduced, and no harmful effects of any kind were observed. Certainly men of the age group of the soldiers could be expected to complain regarding any subsequent disturbance of sexual function. No such complaint is reported.

The evidence summarized in the preceding pages demonstrates clearly that intermittent administration of relatively large quantities of diethylstilbestrol causes no harmful effects in men, women, or children. Permanent or serious side effects are seen only when large doses are given continuously without intermission for long periods of time.

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[30] Andrews, G. C., Domonkos, A. N., and Post, C. S.: Treatment of Acne Vulgaris, J. A. M. A., *146*:1107, 1951.

[31] Savran, J.: Diethylstilbestrol in Prevention of Orchitis Following Mumps, Rhode Island M. J., *29*:662, 1946.

[32] Hoyne, A. L., Diamond, J. H., and Christian, J. R.: Diethylstilbestrol in Mumps Orchitis: Prophylactic and Therapeutic Use, J. A. M. A., *140*:662, 1949.

Fertility in men: Dr. Enders [33] and Dr. Hartman [34] have suggested that on the basis of analogy with experimental animals diethylstilbestrol might impair fertility in men. I am not familiar with any studies made directly on this subject with diethylstilbestrol, although the case of Andrews and coworkers, that of the men treated for acne that I have just mentioned, is apropos.

However, a study with another estrogen throws light on the matter. Heckel and Steinmetz, urologists in Chicago, gave three men 6,000 to 20,000 rat units, which is the equivalent of 1 to 3.33 milligrams of estradiol benzoate three times weekly by injection for periods of 28 to 45 weeks.[35] This estrogen is somewhat more potent when given by injection than is diethylstilbestrol by mouth, and each injection has a rather prolonged action. These men were therefore subjected to the continuous action of rather large quantities of estrogen for many weeks. Now, fertility is determined by the presence of spermatozoa in the semen. In all three of the cases treated with estrogen, there was eventually a very great drop in sperm count; however, with the highest dosage it did not begin until after 40 days, and with the smaller doses, not until after 120 and 200 days, respectively. With the fall there was gradual development of partial impotence, and enlargement of the breasts and nipples occurred. All of these functions and structures returned to normal after administration of estrogen was discontinued. Single doses of even 25 milligrams of diethylstilbestrol would therefore not be expected to have any effect on fertility. Such a dose might, however, temporarily decrease a man's interest in and capacity for sexual activity, but only for 2 or 3 days. A similar temporary decrease in sexual desire and capacity is commonly induced by fatigue or nervous tension. You will recall, in this connection, Dr. Greenblatt's statement before the committee that it requires relatively large doses of diethylstilbestrol to produce temporary sterility. It is my personal belief that there is no practical danger of reducing fertility in men by the intermittent ingestion of even large doses of diethylstilbestrol. This belief extends also to men of impaired or border-line fertility.

Fertility in women: In women fertility depends on the production of eggs. This function is called ovulation. It has been pointed out a number of times before the committee that estrogens are capable of preventing ovulation.[36 37] As Dr. Greenblatt pointed out, diethylstilbestrol—and the same thing holds true for other estrogens—can prevent ovulation only during the ovarian cycle during which it is given. It has been thoroughly established that extremely few women produce an egg every consecutive month. Practically all of them will occasionally have a cycle without ovulation. This failure of ovulation produces no change in the cycle that can be detected by the woman herself. Our knowledge of these occasional lapses has come about through special observations. An occasional cycle without ovulation must be considered entirely normal.

It is well known that women do not normally menstruate during pregnancy. The fact is that this failure of menstruation is associated

[33] Committee hearings, pt. I, 1951, p. 442.
[34] Committee hearings, pt. I, 1951, p. 448.
[35] Heckel, N. J., and Steinmetz, C. H.: The Effect of Female Sex Hormone on the Function of the Human Testis, J. Urol., 46: 319, 1941.
[36] Committee hearings, pt. I, 1951, p. 431.
[37] Committee hearings, pt. I, 1951, p. 461.

with a failure to ovulate. That failure of ovulation is the reason why women practically never carry babies of different ages at the same time. It is generally believed that this failure of ovulation is due to the very large quantity of estrogen which circulates during pregnancy. In other words, the failure of menstruation during pregnancy has the same cause as the failure of ovulation which may be produced by diethylstilbestrol and other estrogens of external origin.

Women do not seem to be necessarily harmed by repeated pregnancies. In fact, the incidence of cancer of the breast is less in women who have borne children than in those who have not. Dr. Greenblatt states:

> I have never seen any harm come to a patient by inhibiting ovulation for a period of 6 months' time.[28]

Neither have I heard of any harm from inhibiting ovulation for such periods. Dr. Greenblatt mentioned 2 milligrams of diethylstilbestrol daily as the necessary dose to prevent ovulation. This is usually given for 8 to 10 days, making a total of 16 to 20 milligrams. The fact is that the estrogen must be taken at just the right time during the cycle. If it is not taken at this time it will not prevent ovulation.

Because of the difficult question of timing and the fact that the drug is not always effective, I do not think there is the slightest danger that this treatment will ever become popular as a means of preventing pregnancy. There are other methods which are very much simpler, more surely effective, and more easily available. It is doubtful if ovulation can be prevented by a single dose of an estrogen, no matter how large. If a woman should, by some chance, eat one or two full-strength pellets at exactly the right time to prevent ovulation, this effect would be produced during that cycle only and is no more than what happens spontaneously at least once in a while in all women.

Skeletal growth: Mention has also been made of the danger of inhibiting growth of the skeleton by ingestion of estrogen. There seems to be a great deal which no one knows on this subject. I am certain, however, that the effects observed in animals cannot be applied directly to man. There is evidence that under certain circumstances continuous treatment with estrogen will stop growth. Under certain other circumstances treatment with estrogen appears to stimulate growth. Dr. Max Goldzieher, of New York, has reported a series of cases in point.[29] The administration of diethylstilbestrol steadily over a period of a few months resulted in retardation or complete cessation of growth in those young women who were extraordinarily tall for their age. On the other hand, the very same dosage of diethylstilbestrol, and I emphasize the very same dosage of diethylstilbestrol, appeared to promote growth in some of the patients who were shorter than normal for their age. It may well be, as Dr. Goldzieher suggests, that the estrogen tends to bring the patient nearer to normal. Certainly, I am not aware of any reports of an undesirable change in growth rate being attributed to the therapeutic use of estrogens.

Cancer of the breast: There has been considerable discussion on the possible effect of estrogens on cancer of the breast. Here again much reference has been made to experiments in animals. Dr. Andrew

[28] Committee hearings, pt. I, 1951, p. 461.
[29] Goldzieher, M. A.: Growth and Sex Hormones, J. Clin. Endrocrinol., *1* : 924, 1941.

C. Ivy, of the University of Illinois College of Medicine in Chicago, makes the following statement:[40]

> One of the best examples of the multiplicity of factors concerned in the induction of tumors comes from the intriguing studies of the natural occurrence of mammary (that is, breast) cancer in many inbred strains of mice. At least three factors are involved: (1) A genetic constitution, or pattern, or inherited susceptibility; (2) the female sex hormone; and (3) the viruslike agent transmitted in the milk of the mice. For example, estrogen must be given to male mice before they will develop the tumor, and spayed females (that is, from which the ovaries have been removed), will not develop the tumor unless given estrogen. Though the inciting agent is present in all of the tissues of the exposed mouse, it predisposes only to mammary tumors. In addition, the age at which the agent is introduced is a factor. Even with the best-known combination of these factors, some 9 months are required for the appearance of the tumor, or the latent period of induction is very long in the life of a mouse. And further, though rabbits and rats form a neutralizing antibody for the milk factor, the mouse does not, and an antimouse tissue serum has no effect on it. Finally, though other factors probably exist, the diet during the period of tumor development exerts an influence on the incidence of the mammary tumors in mice.
>
> Many other examples exist showing the complexity of the endogenous and exogenous factors concerned in the genesis of cancer in mice. To render the problem still more complex, the species differences are marked, and the influence of factors which predispose to cancer in one species may retard in another species. For example, though reproduction and nursing unequivocally predispose to cancer of the breast in the strains of female mice studied, it has the opposite effect on women.

I agree fully with Dr. Ivy's caution against transferring results from one species to another.

Of course, it is true that women have developed cancers of the breast and of the uterus while receiving estrogen therapy. This does not establish a causal relationship any more than the fact that an individual has a heart attack while riding on a streetcar would indicate that riding on streetcars is a causative factor in the production of heart attacks. I have naturally been very much interested in this whole question, and I have not yet encountered a single bit of positive evidence that the administration of estrogen has been a factor in the origin of cancer in human beings. You will perhaps recall Dr. Greenblatt's statement that "I think the men who can speak with greatest authority on it feel that cancer is not produced by administered estrogens."[41]

The effect of estrogen on the growth rate of cancer of the breast already present is a different matter. When cancer of the breast originates before the menopause, even the natural estrogen produced by the woman's own ovaries may accelerate its growth. However, in those cancers of the breast which originate some years after the menopause, the administration of estrogen tends to suppress the growth, and this type of treatment is becoming one of the established methods of attack. Again, I wish to emphasize that estrogens do not cure cancer of the breast. They may merely hold it in abeyance for variable lengths of time. Again, I note that Dr. Greenblatt expressed views similar to mine.[42]

Side effects caused by estrogens: It might be well to discuss one or two of the side effects which may be caused by estrogens. Perhaps the commonest one is nausea, or nausea and vomiting. This side effect

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[40] Ivy, A. C.: Biology of Cancer, Science, *106* : 455, 1947.
[41] Committee hearings, pt. I, 1951, p. 465.
[42] Committee hearings, pt. I, 1951, p. 465.

can be produced by any estrogen.[43] Its occurrence depends partly on dosage, partly on the rapidity with which the drug is absorbed into the system, and partly on the state of the individual. For some unknown reason, women in the menopausal period and women who are susceptible to the nausea of pregnancy are particularly susceptible to nausea from estrogens. Men, nonpregnant women prior to menopause, and children are much less susceptible to nausea from estrogens. Pregnant women are almost immune to it and can take tremendous doses of estrogen without having such symptoms. The reasons for this variation in susceptibility are not known.

It should be pointed out that nausea and vomiting are not necessarily evidence of toxicity. There are certain individuals who experience nausea or vomiting if they take an aspirin tablet on an empty stomach. Certain individuals become nauseated and vomit from a dose of morphine which is entirely safe. Vomiting may be produced as a side effect by many drugs, including certain of the antibiotics such as aureomycin. All these observations emphasize the fact that nausea and vomiting are not necessarily indications that the drug is doing any harm or having any toxic or poisonous effect on the individual.

The next most common side effect is the production of bleeding from the inner lining of the uterus. This bleeding is somewhat like that which occurs during menstruation. The relationship between estrogen and uterine bleeding is a very complicated one. Estrogen can cause bleeding, and estrogen can stop bleeding that is already present. The administration of single doses of 15 milligrams or less will produce bleeding only in women who are predisposed to it from some other condition. Ordinarily it takes about 40 milligrams of diethylstilbestrol administered over a period of a week or two to induce bleeding, and that bleeding does not occur until after administration of the drug has been stopped. I am certain that this group is not interested in the technical details of this subject, but I can assure you that this type of bleeding is not harmful in any way, although it may be inconvenient.

Now, in conclusion, the amounts of diethylstilbestrol that can be obtained from the livers and carcasses of diethylstilbestrol-treated birds are so small as to fall within the physiological, that is, normal range of (1) that which will be taken in an ordinary mixed general diet, and (2) that which is produced within the body. It cannot possibly alter the various body functions in an unnatural or harmful way.

Of course, it is not intended that remains of the pellets themselves will be eaten. It seems to me that the evidence which I have cited demonstrates conclusively that the intermittent ingestion of whole pellets or the remainders of pellets will not produce any permanent or harmful effects on men, women, or children. Diethylstilbestrol is a powerful substance, but so are the estrogens which are produced in the ovaries of women and the testicles of men. The key to the harmlessness of large doses lies in intermittent administration. I am certain that the daily administration of 10 or 15 milligrams of diethylstilbestrol continuously for periods of several years would be harmful and undesirable. However, it has been shown that the ad-

[43] Greene, R. R.: Reactions to Estrogens, Am. J. Obst. & Gynec., 42: 858, 1941.

ministration of even very much larger doses to pregnant women over periods of several months is quite harmless, and there is no reason to believe that the administration of similar doses to non-pregnant women and to men would have permanent effects. We know that the administration of as much as 20 milligrams of diethylstilbestrol in 1 week has no permanent effect on children. I am not aware of any actual experience in the administration of relatively large doses of diethylstilbestrol to children continuously over periods of many months. In the absence of information concerning the safety of such treatment, it would be best to consider the practice undesirable, and I may interject here a comment not as an endocrinologist but as an individual it is hard for me to see how a child would eat the remains of pellets day after day from a chicken neck over a period of many months.

A person can do himself serious damage under certain circumstances by drinking too much water or putting too much salt in his food or doing any one of a number of things which under most circumstances are normal and harmless. For that reason, I would be unwilling to say that anything is absolutely safe. However, it seems to me that the chance of an individual eating the remainders of one or two or more pellets every day, and that means day in and day out, over a period of weeks or months is so remote that it simply does not count against a practice which seems to be desirable from other points of view.

Mr. JONES. We will insert at this point appendix A and appendix B.

(Appendix A and appendix B referred to are as follows:)

APPENDIX A

STATEMENT OF TECHNICAL QUALIFICATIONS OF ROLAND K. MEYER, CONSULTANT, ENDOCRINE LABORATORIES OF MADISON, WIS.

Bachelor of arts Milton College, Milton, Wis., 1926; master of arts in zoology, 1928, University of Wisconsin; doctor of philosophy in zoology and medical physiology, under Dr. F. L. Hisaw and Dr. W. J. Meek, University of Wisconsin, 1930.

National Research Council fellow in the biological sciences, under Dr. G. W. Corner, department of anatomy, University of Rochester Medical School, 1931 and 1932; special fellow in anatomy, Department of Anatomy, University of Rochester Medical School, 1933; research staff, Upjohn Co., Kalamazoo, Mich., 1934 and 1935.

Assistant professor of zoology, department of zoology, University of Wisconsin, 1935–38; professor of zoology, University of Wisconsin, 1938 to the present; consultant, Endocrine Laboratories of Madison, Inc., 1949 to the present.

Graduate training in physiology and endocrinology of reproduction. Post graduate research in the field of endocrinology, specifically endocrinology of reproduction, biological action of steroids and hormone-enzyme relationships.

Twenty years research experience in the above fields represented in part by 130 publications.

Teach general endocrinology, endocrinology of reproduction, and embryology at the University of Wisconsin on a full time basis.

Fellow, American Association for the Advancement of Science. Member of: American Association for the Advancement of Science; American Society of Physiologists; Association Study of Internal Secretions; Society of Experimental Biology and Medicine; American Society of Zoolists; American Association of Anatomists; American Society of Naturalists.

Member Sigma Xi, Phi Sigma, Gamma Alpha; honorary member Phi Beta Pi (medical fraternity).

Extraction and Biological Assay of Beef and Chicken Tissues for Estrogenic Activity—Report No. 1EL–270

Preparation of Extracts

Tissues.—A beef liver and eight chickens were delivered to the office of the Endocrine Laboratories of Madison by Dr. E. D. Campbell. The carton containing the beef liver, which was not sealed, was opened in the presence of Dr. Campbell. (1) Beef liver was labeled "Spec. order of LCB, 4–5–51; Inspector E. B. Meadows." The liver was packed in dry ice and frozen. (2) Chickens were classified as "New York dressed" and were packed in ice. They were eviscerated in the laboratory, and the head of each was examined for the presence of a pellet. A pellet was found in each head. The heads and pellets were removed, and both were discarded. Each carcass, together with its gizzard and heart, was wrapped separately in paper and frozen. (3) The livers of the chickens described above were peeled and frozen. All chicken tissues were rapidly frozen and they, as well as the beef liver, remained frozen until prepared for extraction.

Extraction.—All of the above tissues were ground with sodium sulfate by a hand or power grinder at the rate of 8 grams of sulfate per gram of fresh tissues. The tissue-sulfate mixture was reground once or twice and thoroughly mixed. Entire chicken carcasses with gizzard and heart were ground; heads were not included. The required quantities of tissue-sulfate mixture were extracted with cold chloroform at the rate of 7 cubic centimeters per gram of tissue-sulfate mixture. Extraction was for 15 to 16 hours on a shaking machine. The chloroform was decanted, and the tissue-sulfate mixture washed thoroughly with fresh chloroform (Payne, Endocrinology 45:305, 1949). All chloroform extractions for a tissue were combined and evaporated under vacuum in a water bath. The residue after evaporation was carefully recovered and made up to specific volume with a small quantity of chloroform and stored in the refrigerator until assayed.

Solutions for injection.—The required quantities of chloroform stock solutions were evaporated and residues made up to predetermined volume with corn oil, if necessary. The volume injected for all preparations, including U. S. P. estrone standard, was 0.3 cubic centimeter for each of two injections made 8 hours apart. This volume was set by the volume of oil obtained from the largest dose of chicken carcass extract. Care was taken to prevent leakage. The specific doses of all preparations in terms of fresh tissue and standard estrone are given with the assay results.

Pregnant cow liver was selected as a basis for comparison, as it might be expected to contain some natural estrogen.

Preparation of animals.—Two hundred and thirty young adult female mice obtained from Carworth Farms were ovariectomized and after a period of 2 to 5 weeks they were primed with 0.15 microgram of estrone, and 7 days later they were again primed with 0.15 microgram estrone. All nonreactors to first and second priming were discarded; the reactors were used for assay of the test preparations 7 days after the second priming.

Performance of assay.—Certain phases of the assay were performed by me; others were done under my supervision.

Assay Report No. 1EL–270, July 28, 1951

Client: The Lilly Research Laboratories, Eli Lilly & Co., Indianapolis, Ind.

Samples: Extracts of beef liver, chicken liver, and chicken carcass prepared as described in the preceding section, from tissues supplied to us by Dr. E. D. Campbell, The Lilly Research Laboratories, Indianapolis, Ind.

Procedure: Estrous vaginal smear in ovariectomized primed mice. Administered in two periods of subcutaneous injection.

Diluent: Corn oil.

Results

Group	Treatment	Number of mice		Percent positive
		Positive	Total	
1	Beef liver, 1.189 gram equivalent [1]	10	20	50
2	Beef liver, 1.884 gram equivalent	14	20	70
3	Chicken liver, 2 gram equivalent	10	20	50
4	Chicken liver, 3.17 gram equivalent	19	20	95
5	Chicken carcass, 2 gram equivalent	7	20	35
6	Chicken carcass, 3.17 gram equivalent	11	20	55
7	Estrone, U. S. P., 0.524 international units	15	20	75
8	Estrone, U. S. P., 0.830 international units	19	20	95

[1] Fresh tissue.

Conclusions: It was concluded from a biological assay in ovariectomized mice, of the extracts of tissues submitted to us for assay that:

(1) 1 gm. beef liver is equivalent to 0.263 ± 0.0036 I. U. Estrone, U. S. P., or that 3.802 ± 0.118 gm. beef liver is equivalent to 1.0 I. U. Estrone, U. S. P.

(2) 1 gm. chicken liver is equivalent to 0.239 ± 0.191 I. U. Estrone, U. S. P., or $4.184 \pm .226$ gm. chicken liver is equivalent to 1 I. U. Estrone, U. S. P.

(3) 1 gm. chicken carcass is equivalent to 0.127 ± 0.0335 I. U. Estrone, U. S. P. or 7.874 ± 0.740 gm. chicken carcass is equivalent to 1 I. U. Estrone, U. S. P.

THE ENDOCRINE LABORATORIES,
ROLAND K. MEYER,
Consultant.

APPENDIX B

This is to certify that the following results of tests for estrogenic substance in the tissues named below are true copies of the experimental protocols made for Wick & Fry, Inc.

In reporting this work we believe it advisable to establish the qualifications and technical background of Dr. Edward D. Campbell, Ph. D. and Mr. Harry Wick who are the individuals responsible for this assay. Dr. Edward D. Campbell obtained his Ph. D. degree from the University of Chicago in 1924. His minor work for the degree was in biochemistry under the late Dr. F. C. Koch. He joined the Ely Lilly & Co. research staff in 1925 and is now director of the division of biochemical research. Mr. Wick became associated with Dr. Campbell in 1926 and since that time they have continuously made quantitative sex hormone assays. Also, during this 24-year-period they have carried on collaborative work involving assays for periods of a year or more with the following specialists in the estrogen field: Dr. G. N. Papanicolaou, Cornell Medical College, New York City; Dr. H. M. Evans, University of California, Berkeley; Dr. J. B. Collip, McGill University; Dr. E. A. Doisey, St. Louis University School of Medicine.

White Rock cockerels 7 weeks of age were implanted with one "Capette" (R) pellet. Six weeks later the chickens were dressed out and the livers collected for testing. Previous testing and also work published by S. Bird, L. I. Pugsley, and M. O. Klotz (Endocrinology *41* 282 1947) had shown that diethylstilbestrol is rapidly excreted and even when fairly heavy doses of the drug were administered not enough of the drug is to be found in the tissues to afford a test on rats. It was also shown that estrogens tend to concentrate in the liver, skin and adipose tissue and that an assay on one of these tissues can serve as an index for residual estrogen in the whole carcass. Therefore, in the work reported here the liver was the tissue of choice and the mouse, which is about ten times more sensitive than the rat, was used as the test animal.

The chicken livers are ground with anhydrous sodium sulfate until quite friable, extracted with chloroform for 20 hours, the chloroform was evaporated and the estrogen was taken up in cottonseed oil to a volume of 10 ml. for test on mice according to the method used by the St. Louis University School of Medicine for licensees under the Letters Patent 1, 967,350.

The estrone E. $D._{50}$ (the dose necessary to produce estrus in 10 out of 20 mice) in our colony using oil solution is .06 micrograms. This is called one mouse unit. The diethylstilbestrol E. $D._{50}$ in our colony is .08 micrograms.

The estrogenic activity extracted from the tissues probably represents a mixture of both natural estrogens and stilbestrol. The following chart states the amounts in both estrone equivalents and stilbestrol equivalents:

Group	Weight of liver	Equivalent of estrone per liver	Equivalent of estrone per gram of liver	Equivalent of diethylstilbestrol per gram of liver
	Grams	*Micrograms*	*Micrograms*	*Micrograms*
1	56.5	3.67	0.065	0.085
2	45	4.05	.090	.118
3	48.5	4.12	.085	.113
4	43.2	4.02	.093	.124
5	44.6	3.61	.081	.108
6	46.4	2.78	.060	.080
7	58.5	4.97	.085	.113
8	36.2	2.20	.061	.081
9	38.8	3.49	.090	.118
10	44.5	3.56	.080	.107
11	42.5	5.01	.118	.151
12	42.6	3.79	.089	.118

Livers from another group of 10 chickens treated at 6 weeks of age and dressed at 12 weeks of age, were pooled. The average liver weight was 47.4 gms. and an aliquote sample assayed .08 microgram estrone equivalent per gm. or an average of 4.0 micrograms estrone equivalent per liver.

When individual livers of untreated control cockerels were tested, not enough estrogen was found to give a test. Individual tests were obtained on untreated turkey livers and some estrogen could be demonstrated because of their larger size. A typical assay was .026 microgram estrone equivalent per gm. on a 75.5 gm. liver from a Broad Breasted Bronze hen 6.5 months of age. Another hen of the same age treated with one "Capette" pellet 6 weeks previously had a liver of 101.5 grams, which assayed .05 microgram estrone equivalent per gm.

Also by way of comparison, a sample of Government-inspected liver from a pregnant cow was obtained at Kingan & Co., Indianapolis, Ind. Two assays were made and the values .36 and .33 micrograms estrone equivalent per gm. were obtained.

The carcass of chickens 7, 8, and 9, including bones but not viscera, were ground and extracted. No estrogenic material could be demonstrated in any of the three samples.

WICK & FEY, INC.

Mr. JONES. Any questions? Dr. Miller would like to ask some questions.

Dr. MILLER. I have to leave soon, and I would like to ask some questions.

You are on the research staff of Eli Lilly & Co.?

Dr. HINES. That is right.

Dr. MILLER. Does Eli Lilly & Co. make diethylstilbestrol?

Dr. HINES. They do.

Dr. MILLER. Do they sell it to the drug trade and physicians?

Dr. HINES. Yes.

Dr. MILLER. Do you know what are the indications for its use which they recommend or you, as the director of research, recommend?

Dr. HINES. Yes; I have it down here in the early part of my statement.

Dr. MILLER. Well, they were rather vague. Could you go over them again briefly?

Dr. HINES. Menopausal symptoms, functional uterine bleeding, senile vaginitis in women, prevention or treatment of painful engorgement of the breasts in women after childbirth, as a palliative treatment for cancer of the breast in women, as a palliative treatment for cancer of the prostate in men.

Dr. MILLER. Yes.

Dr. HINES. There are other minor indications and situations where it might be helpful, but those are the principal indications.

Dr. MILLER. Very well.

You are familiar with medical literature on——

Dr. HINES. In fact, I write the medical literature that our company puts out on that subject.

Dr. MILLER. Are you familiar with the material put out through the American Medical Association?

Dr. HINES. Yes; definitely.

Dr. MILLER. Do you know of any articles published recently or any men who disagree with your views as to the effect of diethylstilbestrol?

Dr. HINES. Well, as a matter of fact, I do not think I presented very many of my views. I quoted the work that other men have done, and the observations that other men have made on the uses.

Dr. MILLER. Do you know of any endocrinologist who believes that the use of diethylstilbestrol should be curtailed or prohibited?

Dr. HINES. Oh, I am sure there are some; I am sure there must be.

Dr. MILLER. Do you know whether diethylstilbestrol is permitted to be used in Canada for implantation in chickens?

Dr. HINES. I know nothing about that.

Dr. MILLER. You know nothing about the results they had in Canada, of the experiences in Canada?

Dr. HINES. Well, I have discussed this article of Bird, Pugsley, and Klotz, and I have shown that there is nothing in that article which can be used as evidence against the use of diethylstilbestrol in chickens.

Dr. MILLER. You know Dr. Enders testified before our commitee——

Dr. HINES. Yes.

Dr. MILLER (continuing). And qualified himself as an expert, professor of zoology, I believe, at Swarthmore College?

Dr. HINES. Yes; but I might point out that Dr. Enders is not a physician. I do not believe he has had experience with administering the drug to human beings.

Dr. MILLER. Well, he is a fellow of the Academy of Natural Sciences of Philadelphia. He has held a number of important posts. He qualified himself, at least, and I want to read the third paragraph on page 430, in the hearings before this committee between April 12 and June 19, 1951, the following excerpts from his testimony:

Dr. ENDERS. The supporters of the use of diethylstilbestrol always cite that the drug is used in medicine with inference that it is therefore harmless. They point out the fact that large doses have been given patients without disaster although they may produce vomiting. They never mention the fact that small amounts, even minute amounts, given over a longer period may give results that differ from those where larger dosages are given under the supervision of a physician. Yet, the literature shows that extremely minute doses can effectively sterilize and injure laboratory animals where larger doses have no long-range effect. These small doses do not produce vomiting. Nor do the supporters quote a leading endocrinologist who says:

"In women there is evidence that estrogens are concerned in the etiology of mammary cancer. Not only does the clinical evidence point to such a conclusion, but now, with the lapse of time, cases are being reported in which cancer of the breast has followed prolonged treatments with estrogens."

Were you familiar with that statement?

Dr. HINES. Yes; I have read that.

Dr. MILLER. You disagree with it?

Dr. HINES. I would point out that Dr. Enders' observation on the effects on fertility are with respect to animals; he says so. I do not believe that Dr. Enders has had any experience with people, and I have tried to make clear from a number of examples here that that is the sort of thing one cannot carry over from animals to people.

Now, the statement has been made that estrogens are, perhaps, connected with cancer of the breast in human beings, but that is a different thing from saying that the ordinary therapeutic use of estrogens has caused cancer.

Dr. MILLER. Do you know whether the use of your estrogens are on the increase or decrease among physicians?

Dr. HINES. I think it is on the increase. I have here figures from the United States Tariff Commission on the total sale of diethylstilbestrol in the United States. In 1946 the figure is 500 pounds; in 1949 it is 1,100 pounds.

Dr. MILLER. That is the Tariff Commission for export?

Dr. HINES. No; that is total sales in the United States, production of the chemical. So, I would say it was on the increase from these figures, very great increase.

Mr. KLEINFELD. Does that include use in chickens?

Dr. HINES. That includes that; there is no way of separating that out.

Dr. MILLER. On page 431 of the same hearings, the fourth paragraph, it says:

> While it has been conceded that enough of the drug can depress the growth of children, cause sterility in men, cause cystic ovaries, cystic breasts, cystic kidneys, and suppress ovulation, it is difficult to prove this because one does not knowingly experiment with the human. However, experiments with animals confirm these findings.
>
> Nevertheless, no one contends that the large doses so far used to produce these conditions could be ingested in chicken.

Then he continues:

> Now that experiments with minute dosages indicate this danger such conditions may be reported for humans if they ingest small doses over a long period.

Has it been shown that in animals cystic kidneys, cystic ovaries, and cystic breasts are produced?

Dr. HINES. I am not familiar with the production of cystic kidneys in animals through estrogens. I am less familiar with the effect of estrogens in animals than in human beings.

I can point out some very recent work in the golden hamster with diethylstilbestrol and one other estrogen that will produce certain kinds of tumor, and it does not produce that kind of tumor in any other species that these investigators have yet tried.

No other estrogens than these two, and one of them is a natural one and one of them is a synthetic one, do that in that particular animal.

Now, it is possible by continued administration of estrogen in women, in some circumstances and in some instances, to produce cystic ovaries, but that is by long-continued administration. As a matter of fact, there is some evidence that when the ovarian function gets out of rhythm and ceases to be cyclical a steady production of estrogen may take place in the ovary that does produce cysts of the ovaries; but that is a case of continuous unremitting administration, and it has been found, if they can break that cycle and give the ovaries a periodic rest, this condition disappears.

Dr. MILLER. In your opinion, have we experimented sufficiently with it to permit its use in food?

Dr. HINES. I think so. It has been in use for 12 years. At the end of the first two, we submitted to the Food and Drug Administration reports on its administration to 8,000 cases. My card file for diethylstilbestrol, in which each card represents a published article, is that long [indicating a distance of 12 inches].

Dr. MILLER. On page 432 of the same hearings, Dr. Enders says this:

> I believe that the use of this synthetic hormone in food should be prohibited until more research has been done by disinterested men. In the meantime I am convinced enough of the possible harmfulness to refuse to buy such poultry for family use.

You would disagree with that?

Dr. HINES. I would say this: The work that I have been quoting here has all been done by disinterested men, and I do not like to say this, but I do not think that anyone whose training has been entirely on animals, and whose experiments have been entirely on animals, is qualified to speak with regard to the human being. There is too much difference.

Dr. MILLER. Yes.

Dr. HINES. Sometimes the men whose work has been limited to animals do not appreciate that difference because they have not been on the other side of the fence and seen it.

Dr. MILLER. Well, let us quote another man, Dr. Carl G. Hartman.

Dr. HINES. Dr. Hartman is a zoologist, too; he is not a physician.

Dr. MILLER. He is a doctor of philosophy and qualified as an expert.

Dr. HINES. An expert in zoology.

Dr. MILLER. You quoted Dr. Bird and Pugsley.

Dr. HINES. Yes.

Dr. MILLER. Let me quote them for you. Here is what he said they said. This is at page 445 of the same hearings, next to the last paragraph:

> Bird, Pugsley, and Klotz had menopausal women with atrophic vaginae eat eight caponet livers for 3 days; on the sixth day vaginal smears showed cornification, which reached its height on the eleventh day.
>
> Estrogens affect the pituitary, inhibiting all of its functions; that is, its output not only of gonadotropic (ovary and testis stimulating) hormones, but also growth hormone, thyrotropic, adrenotropic, ketogenic hormones.
>
> Estrogens affect enzymes on which all bodily functions depend, inhibiting, for example, the important oxidases and dehydrogenases.

Was he quoting Bird, Pugsley, and Klotz?

Dr. HINES. I am again sorry to have to say this, but he was misquoting Bird, Pugsley, and Klotz. I have their reprint here, and any of the members of the committee can see for themselves.

Dr. MILLER. I went over the reprint. I have it in my office.

Dr. HINES. The experiments of Bird, Pugsley, and Klotz do not include experiments on birds that were implanted with pellets. There are no such experiments in this article.

Dr. MILLER. Do they include some experiments on women?

Dr. HINES. Yes, and what they did was to feed to these women the livers of birds that had been fed large quantities of dimethyl ether of diethylstilbestrol, as I have explained in my statement.

Dr. MILLER. What was the effect of eating it?

Dr. HINES. It had a slight estrogenic effect. But the point that I started to make this morning is that the dimethyl ether of diethylstilbestrol is metabolized entirely differently from diethylstilbestrol itself, and the dimethyl ether, because of the presence of these methyl groups which protect the compound from being destroyed, stays a long time in the body and like the DDT that you heard about this morning, and like other things that are soluble in fat when they cannot be gotten rid of, the dimethyl ether of diethylstilbestrol is stored in the fat, and then comes out slowly, and, of course, the liver is the place where these things are all metabolized, and, naturally, it would be concentrated in the liver, and when they fed the fat and the livers of these treated animals, of course, they got estrogenic effects.

Bird, Pugsley, and Klotz themselves did not use pellets, but they injected a solution of diethylstilbestrol in oil into the bird, and then they analyzed the fat. That is the only part they analyzed, and when they analyzed the fat they found that there was no diethylstilbestrol whatever in the fat; so that the experiments with the dimethyl ether just do not apply, have no relation whatever to the implantation of pellets of diethylstilbestrol itself.

Dr. MILLER. Doctor, do you think there is any need for any new legislation covering the stilbestrols, estrogens, and so forth?

Dr. HINES. I personally do not; I personally do not.

Dr. MILLER. Are you familiar enough with the chemicals and pesticides used in and on food?

Dr. HINES. That is a subject I do not know anything about.

Dr. MILLER. Are you an endocrinologist? Would you call yourself an endocrinologist?

Dr. HINES. I guess so.

Dr. MILLER. You overlap a little bit. It is an interesting subject, and I am all for progress if we can make it, in medicine.

As a medical man I know there has been a tremendous amount of progress in the last few years, ever since I came to Congress, but I get a little concerned sometimes about how fast we go, and while I realize that Eli Lilly & Co. is a very reliable firm, there are some drug groups on the fringe also making some form of estrogens and the glib salesmen go out and sell them for face creams and perhaps for the treatment of hemorrhoids, and I am not sure but what some restraining hands should be laid upon those on the fringe who might do some harm to those who are told to use estrogens in various forms.

Dr. HINES. Well, as far as their use in medicine by doctors is concerned, I think the Food and Drug Administration is doing a very good job policing that, and I would like to say further that the views, the evidence, I have presented here do not stem from Eli Lilly & Co. No one there saw this paper, asked me about it, told me what to say.

Dr. MILLER. Well, of course, it would naturally represent——

Dr. HINES. This represents my own work entirely.

Dr. MILLER. But you have been employed by them for 13 years, and it naturally would represent their views or you would represent their views and tell them what to think on the subject.

Dr. HINES. That is right. I tell them what to think rather than the other way around.

Dr. MILLER. Tell them what to think, so these are your views from you.

Mr. McDonough. Doctor, you said that the Food and Drug Administration was policing the use of estrogens and stilbestrol in medicines very well.

Dr. Hines. I think they are.

Mr. McDonough. What we are talking about is the use of stilbestrol in commercial products and in many instances in products where the people do not even know they are absorbing them. Do you think, as a medical man, that because stilbestrol is a drug and has a therapeutic effect on the human system it should be controlled equally in the food industry as it is in the drug industry?

Dr. Hines. Well, I do not know quite what you mean by fully controlled.

Mr. McDonough. Your opinion is that in the use of stilbestrol as a drug existing law is doing a good job in protecting the public interest. But do you think that same policing and same control should be in the use of stilbestrol where the public does not even know they are getting it? There is no doctor who prescribes it. It gets into the food, and someone may get an overdose of stilbestrol through the eating of livers of chickens and other animals that may be injected with it, or the use of cold cream which they buy over the counter, and there is not any medical advice from that source at all.

Now, do you think the same control ought to be applied?

Dr. Hines. Well, I must say I do not know anything about the cold cream end of it, because that is a phase of it that I have not followed at all.

Mr. McDonough. The question I am asking is, that since the public gets it without any control or direction of a physician through the use of food that has had it injected and other sources, this same control ought to be applied there as in the use of drugs.

Dr. Hines. I do not see how you can exercise the same control.

Mr. McDonough. Do you think there is any need for control of it when used as a drug?

Dr. Hines. Oh, yes; definitely.

Mr. McDonough. Then there certainly ought to be controls where it is not used and sold to the public as a drug.

Dr. Hines. Let me say this: That the amount that one can get in the carcass of the bird and in the liver of the bird is, it seems to me—I think the evidence is quite clear on it that that is within the range that people are being subjected to all the time. I do not see that there can be any possible objection to that negligible quantity, and it is so small that it cannot even be detected in some lots of birds.

Now, then, the other thing is when they get a residue of pellets. As far as I can see, that is the only thing that there need be any concern about.

Mr. McDonough. That is a remote possibility, you think?

Dr. Hines. Well, if the pellets are implanted where they are supposed to be, I think it is a remote possibility.

Mr. McDonough. Do you think there should be any legislative control of implanting the pellets in the proper position in the bird or the animal?

Dr. Hines. Well, I suppose it might be in order to have some kind of an inspection.

Mr. McDONOUGH. In other words, you are recommending that some sort of inspection be made of animals in which pellets are injected to be sure they are put in the right place?

Dr. HINES. I do not know that I would want to go on record as saying that I recommend it, but that is certainly a possibility of what could be done.

Dr. MILLER. Where would the proper place be, Doctor? Where would the proper place be to inject it in the necks of chickens?

Dr. HINES. Again, here I am getting out of my field, and that is where I feel I am not qualified to say very much.

Dr. MILLER. Presently they put it right behind the ear; I saw some of it at home. I put a few of them there myself. It is very interesting.

Dr. HINES. On that phase of it I speak as a layman and not as an expert, but it seems to me that is the common sense place to put it.

Dr. MILLER. There are some people in some groups, you know, who boil the whole chicken head and make soup out of it, so they get the benefit of all the crystals that are unabsorbed and fall down on the bottom, and get a big dose of it. They live on chicken heads, and boil the whole head.

Dr. HINES. If they take all of the sediment, they are taking all of that stilbestrol.

Dr. MILLER. Would that be good or bad?

Dr. HINES. What I point out here is that if they get it intermittently it would not do them either good or harm.

Dr. MILLER. Sort of a neutral product?

Dr. HINES. That is right.

Dr. MILLER. You would really want to say it is neutral?

Dr. HINES. That it does no good and no harm if it is intermittent.

Dr. MILLER. I see.

Mr. McDONOUGH. Are you familiar enough with the meat that is produced by the injection of a stilbestrol pellet in a chicken to know that it is a better quality or equal quality to the meat produced without stilbestrol?

Dr. HINES. I have not made a study of it; but we have had some that were treated, and as far as I could tell it tasted just as good. I do not know. There is a report on that made by some men at Purdue, Detwiler, Andrews, and Bohren, which appeared in Poultry Science, volume 29, page 513, July 1950, and they studied the influence of thiouracil and stilbestrol on broiler quality, and I am just quoting them, but here is what they say:

> In general, stilbestrol-treated birds gained more rapidly than the controls. When caloric intake of feed was compared to the caloric composition of the edible carcass, caloric efficiency was increased 20, 30, and 50 percent by stilbestrol, thiouracil or the thiouracil-stilbestrol combination, respectively.
>
> Thiouracil or stilbestrol alone consistently improved carcass quality, but the combination of these two substances was superior to either administered separately.
>
> Fat deposition and dressing percentage were increased by all experimental treatments and protein and moisture were decreased.

Now, I am simply quoting these professors at Purdue, and if you want this reprint for your files, here it is. But I do not know anything about it as an expert.

Mr. McDONOUGH. We had some testimony before the committee—I have forgotten who it was—who stated that the meat produced by

the stilbestrol pellet was stringy and tough, that it was not the same quality as the natural meat.

Dr. HINES. I do not know about that.

Mr. MCDONOUGH. I wish you scientists would get together. You have so many different opinions, and the committee does not know whom to believe.

Dr. HINES. These things are so specialized that every man has to concentrate on one field, and I think we get into trouble when scientists who are expert in one field get over and get to testifying in a field that they are not familiar with, and I am trying to avoid that.

Mr. HORAN. Dr. Hines, you are aware, of course, that the work of this committee is to find out how we may first determine what is beneficial for the public health, how we can find out that thing first, so that we can be more reassuring to the people of the Nation and make the work of the Food and Drug Administration in enforcing that which is good and beneficial for the public, make their work easier, too, and more authentic.

How, in your opinion, can we bring the work of the men whom you have quoted here, and the pamphlet from Purdue University that you just read, how can we bring them together in such a way that the findings of these men will become public knowledge, they will be coordinated, and we then recognize it as something we can believe, and then the Food and Drug Administration, based upon the findings of an unbiased body, might modify or enlarge their administrative and enforcement policies? How can we do that?

Dr. HINES. Well, you see, there is a subject where I am no more expert than anybody else is.

Mr. HORAN. But you are interested, I know, in that final answer.

Dr. HINES. Yes; that is right. The reason I have been willing to come here is to have you receive the benefit of the knowledge that I have accumulated over this period of time on the actual effects of diethylstilbestrol on human beings.

Now then, when it comes to how to disseminate that knowledge and how to use it, that is another problem that I have not given any study to.

Mr. HORAN. Don't you see that is the problem we have, and that is how to coordinate and to make recognizable the findings of men of science regarding these things that do exist in this great Nation of ours, so that we can say, "Here is a balanced opinion of the minds most apt to throw more light on a given subject."

Did you ever read, One Hundred Million Guinea Pigs?

Dr. HINES. Yes.

Mr. HORAN. It caused a lot of damage in this country; it hurt a lot of industry. It was the sort of thing that Dr. Cox was talking about this morning.

Now, we should have facilities for giving the lie to those who are telling untruths on either this side or that side——

Dr. HINES. That is right.

Mr. HORAN (continuing). Of the question.

Dr. HINES. I do not know—I suppose there must be some way of summarizing all this material and making it available, but what the exact procedure should be, I do not know.

Mr. HORAN. In the field of pesticides, you are aware, of course, as it was mentioned this morning, that we have tried increasingly to make

use of one of the facilities of the Federal Security Agency, the Public Health Service, to conduct all manner of experiments in the application and the use and the effect of pesticides, and we find many willing people in the communities where industries are trying to master the use of pesticides and to master also the technique necessary to make them safe, absolutely safe, for human consumption. My State was given somewhat of an accolade this morning, of which I am very proud, but into that has gone a quarter of a century of rather intense living with that subject.

You have been living with this subject for 12 years. Who would you want to say that your product is safe?

Dr. HINES. I am afraid I do not understand that.

Mr. HORAN. Would you want some Federal facility to exist that could take this work and, perhaps, verify it, and then certify it? This is a practical question, in my opinion, because of the work of this committee, it must necessarily move in that direction, otherwise we flounder, you see—

Dr. HINES. Yes; that is right.

Mr. HORAN (continuing). In a sea of suspicion and doubt.

Dr. HINES. Well, I do not know.

Mr. HORAN. I am going to leave it, Mr. Chairman, just as I left it with those in the cosmetics industry, who might suffer the same way. We are going to continue our work for some time yet, at least, and I would like to have reputable firms like your own company come out with some conclusions in that direction. Then we will have arrived some place on firm ground, don't you see.

Dr. HINES. Yes; I see what you mean, and I am sorry I have nothing to suggest.

I will say this: That Eli Lilly & Co. stick very strictly to the supplying of medicines for use on the doctor's prescriptions. They do not make any appeal to the public; they do not have direct dealings with the public, so that they, perhaps, would not consider that this fell within their sphere of influence.

Mr. HORAN. Any case that I did not think was accidental in the use of drugs which have to do with reproduction in any field is apt to be based, in the final analysis, on vanity in one way or the other, is that not true?

Dr. HINES. I think I understand what you mean.

Mr. HORAN. The Food and Drug Administration, of course, tries to apprehend and to correct those things as best they can, but there again they are faced with enforcing some regulations that they have had to dig out of thin air, perhaps, in some instances, because there are differences of opinion.

Now, the cosmetic industry, it has possibly one avenue of escape from their dilemma, and that is the AMA committee on cosmetics. It would appear to be a very commendable start. It is not old, but it is a direction that we might move by clothing that body with the proper authority and thereby having a board that could clear these things.

It has been suggested that pesticide commission or something be set up to pass on these things finally. But you have no answer really at this time?

Dr. HINES. No, I have not; I am sorry.

Mr. HORAN. But you will think about it?

Dr. HINES. I will, indeed.

Mr. HORAN. Thank you.

Mr. JONES. Just one question. I realize you are not a poultry specialist, and that is not in your field, but I just wondered as a person who has made a study of this stilbestrol, do you think it would be possible in the injection of that little pellet to include some kind of a dye or something that would be absorbed by the tissues around there to give notice that that bird had been injected with that pellet, possibly a green dye or something like that, that would provide a warning to the public—do you think it would be possible for such a thing as that to be included in a pellet like that?

Dr. HINES. Well, I would presume that such a substance might be found. It would have to have several characteristics. I am giving you an off-the-cuff opinion here which, on further reflection, I might want to change. But in the first place it would have to be harmless to the chicken, and I would say would have to be a dye that was harmless to people too, in case they ignored the warning of the color.

Mr. JONES. Now, we have Easter egg dyes which are supposed to be harmless when they are eaten, and with something similar to that which would make a spot around there, then people would have a warning, at least, not to eat that portion of the bird. Would that be a practical suggestion or not?

Dr. HINES. Well, if there is something that is harmless and would stay at that site for that long a period of time. You see, that stain should stay 8 weeks, and to be certain it ought to stay longer.

Mr. JONES. If a man has a tattoo mark put on, he has a mark for life. Would it be possible to get something like that? Apparently that ink or dye that is used in the tattooing process, is possibly not harmful, and I thought maybe we could include a dye in this pellet which would spread to this spot, and would furnish a warning to the people.

Dr. HINES. There is one difference there, and that is that the pigments that get into the skin in tattooing are not removed as rapidly as pigments that are put in the tissues under the skin.

Mr. JONES. I see.

Dr. HINES. So it might be a problem to find something that would remain at that site that long and would not be taken up by the white blood cells which are the things that normally remove particles of foreign substance.

Mr. JONES. Well, that is a little off the subject, but I have had that on my mind for some time, and thought we could work out some way, and then the people would have a distinct warning and, of course, they might not even want to buy any of the birds if they had that, but at the same time they would know that area of the bird was not to be eaten, and it might serve a useful purpose.

Dr. HINES. I think that is a very promising suggestion to follow up and study. I do.

Mr. JONES. As I understand it, you are appearing here and not proposing to be an expert on the use of this drug on animals, but giving us the results of your views and other medical men of the action or reaction of the chemical on human beings.

Dr. HINES. That is it exactly.

Mr. JONES. I have no more questions.

Mr. Gottlieb?

Mr. GOTTLIEB. Dr. Hines, are you a practicing endocrinologist?

Dr. HINES. Not at the moment.

Mr. GOTTLIEB Have you ever been?

Dr. HINES. In a sense, yes.

Mr. GOTTLIEB. What does that mean?

Dr. HINES. Well, I mean by that that for several years before and during the early part of the war I did, and then because of the pressure of other work I had to drop the clinical work. I am expecting to pick it up again very soon.

Mr. GOTTLIEB. In your clinical work did you use diethylstilbestrol?

Dr. HINES. Yes, I did.

Mr. GOTTLIEB. As I understood your previous testimony you have not conducted any experimental work using stilbestrol, which has been published, is that correct?

Dr. HINES. That is right.

Mr. GOTTLIEB. What you have done in your statement is just compiled the published works on the subject, and attempted to correlate it in some manner with the use of stilbestrol in chickens.

Dr. HINES. I have added to that published work the results of attending a great many meetings, of discussing this subject formally and informally with a great many people who are themselves doing work on the subject. Sometimes I think one gets a better perspective on the subject by talking to a great many people who are more deeply immersed in smaller and specific problems than one does if he is immersed in those himself.

Mr. GOTTLIEB. Doctor, Appendix A, attached to your statement is an assay or what purports to be an assay——

Dr. HINES. I have the originals, signed originals, here if anybody wants them.

Mr. GOTTLIEB. Just let me finish the question, please. That is an assay of the flesh of chickens which have been treated with stilbestrol by pellet implantation, is that not correct?

Dr. HINES. That is right.

Mr. GOTTLIEB. I take it that the first few pages of Appendix A contains a report of the laboratory that did this work?

Dr. HINES. That is right.

Mr. GOTTLIEB. I understand there were eight chickens involved, is that correct? The first sentence says:

A beef liver and eight chickens—

Dr. HINES. That is right, eight chickens.

Mr. GOTTLIEB. Further on it says:

A pellet was found in each head. The heads and pellets were removed and both were discarded.

Would you tell us, please, what was the weight of each of these pellets found in the heads?

Dr. HINES. I have no idea.

Mr. GOTTLIEB. Is that not a rather important point?

Dr. HINES. No, I do not think so.

Mr. GOTTLIEB. Doctor, suppose that the pellets in each of the chickens weighed 10 milligrams. Would that have any effect upon the assay of the flesh and the liver of those chickens?

Dr. HINES. Now, you mean if a pellet, a 15-milligram pellet, which contains, in the case of the Wick and Fry pellets, I am told, 12 milligrams, and then at the end of 6 weeks, if——

Mr. GOTTLIEB. I am not going that far. I am taking the statement here, and it says that a pellet was found in the head and that the heads and pellets were removed and both were discarded.

I want to know if you can tell me whether there would be any effect on the assay of the flesh if each of these pellets had weighed 10 milligrams?

Dr. HINES. I do not think one can make any statement without more information than just that.

Mr. GOTTLIEB. Well, would not this assay show less estrogen in the flesh if 10 milligrams were in the pellet that had not been absorbed?

Dr. HINES. That depends on how long the pellet has been in there.

Mr. GOTTLIEB. All right.

How long after the pellet implantation were these chickens slaughtered?

Dr. HINES. Well now, I do not know whether it is in here or not.

Mr. GOTTLIEB. I could not find it, Doctor. Do you know from your own knowledge?

Dr. HINES. Well, all I know is what Dr. Campbell told me, and he said it was 6 weeks.

Mr. GOTTLIEB. Let us assume then that the period of implantation was 6 weeks, and that a 15-milligram pellet was implanted.

Dr. HINES. Yes.

Mr. GOTTLIEB. Let us assume that 10 milligrams of unabsorbed pellet remained in the head upon slaughter. Let us assume another case in which the same period of time elapsed between implantation and slaughter.

In the second example, a half-milligram pellet remained unabsorbed. Are you stating, Doctor, that there would be no difference in the assay of the flesh and the liver of those two chickens?

Dr. HINES. I do not know whether there would or not. One can presume that there has been a more rapid rate of absorption when there is less left after the same period of time.

Now, here again, this is work that I have not done myself, that I have had no contact with, but it is my understanding that studies that have been conducted by Wick and Fry and, perhaps, by others, indicate that the rate of absorption of these pellets is quite uniform, and that there is not very much variation in the residues that are found after a definite period of time.

Mr. GOTTLIEB. Are you familiar with the recent seizures in New York City of several thousand pounds of chickens by the Food and Drug Administration?

Dr. HINES. I read something about it. That is all I know about it.

Mr. GOTTLIEB. Suppose I told you that the Food and Drug Administration found, and there was testimony to that effect before this committee in New York several weeks ago, that a comparatively large percentage of chickens were found to have been implanted with stilbestrol pellets in areas other than the base of the skull, and in some cases as many as four pellets were found remaining unabsorbed in the chickens that were on the New York market ready to be sold to the consumer. Do you think that constitutes any hazard?

Dr. HINES. From what point of view? You mean from the residues?

Mr. GOTTLIEB. Do you think that the sale of such chickens constitutes a hazard to the consumers, any part of them or all of them?

Dr. HINES. Well, now, are you referring to the content of the tissue, the tissue content of estrogen?

Mr. GOTTLIEB. The whole business. They sell a whole chicken. Do you know what New York dressed poultry is?

Dr. HINES. No; I am afraid I do not.

Mr. GOTTLIEB. It is head on, feet on, and guts in. That was testified to before this committee by Dr. Byerly, I believe.

Dr. HINES. Well, I did not read that testimony.

Mr. GOTTLIEB. You can accept that as a fact.

Now, these chickens are sold in New York City in that manner, and in those chickens there have been found as many as four unabsorbed pellets in areas other than the base of the skull.

If a large percentage of chickens are sold in that manner to consumers, do you think that constitutes any hazard to the consumer?

Dr. HINES. It might possibly.

Mr. GOTTLIEB. Then you think that the Food and Drug Administration was warranted in seizing these chickens?

Dr. HINES. Well, I do not know that I would venture an opinion on that.

Mr. GOTTLIEB. If it might be posible be hazardous, do you think that the Government should permit these chickens to be sold to the unsuspecting public?

Dr. HINES. I am not sure that they would constitute a hazard.

Mr. GOTTLIEB. Then is it your testimony that it does not constitute a hazard?

Dr. HINES. No; I am saying that I am not sure.

Mr. GOTTLIEB. You quoted Dr. Greenblatt at great length in your statement. Do you know that Dr. Greenblatt was quite emphatic on the point that there should not be any pellet residues going to the consumer?

Dr. HINES. Does that appear in there?

Mr. GOTTLIEB. Yes. It does. Have you read his testimony?

Dr. HINES. I read it. If I read that, I have forgotten about it.

Mr. GOTTLIEB. Do you think that he has any basis for making that statement?

Dr. HINES. Well, I have considerable respect for Dr. Greenblatt. I have offered you evidence here to the effect that intermittent injection of the amounts of diethylstilbestrol that might even by an outside chance remain, not might just reasonably remain, but was at all likely to remain, if taken intermittently will do no permanent harm.

Mr. GOTTLIEB. Let me read to you part of the testimony of Dr. Greenblatt whom you quoted. He said at page 468:

> I feel if you ingest that area where there is a concentration of the crystals, or where some part of the pellet may be still remaining, you are actually feeding the patient with steroid material.

Later on he said:

> I think that we are dealing with hormones that change the physiologic status of the patient. As I have already pointed out, we cannot allow every Tom, Dick, and Harry to use stilbestrol, or estrogen or these hormones. We can't allow anyone to come in and say, "Why can't I put it in face cream? Why can't I put it in alcohol and have it as a drink?" Or whatever he wants to do with it. I think it should not be allowed to be used injudiciously, or for any purpose, without a thorough understanding of why and in what amount and without good advice.

Are you in agreement with Dr. Greenblatt on that point?

Dr. HINES. I am in agreement with part of that, and the part where it applies to well, let us say, face cream, or something that is going to be used continuously, that is where I think there is a tremendous distinction. It is the continuous administration that can do harm.

Mr. GOTTLIEB. Doctor, you criticized the Canadian experimental work——

Dr. HINES. No; I beg your pardon, I have not criticized that work at all. What I have criticized is some misreading of the results.

Mr. GOTTLIEB. I have not completed my question. I say you have criticized the Canadian work of Bird, Pugsley, and Klotz because it has been used to correlate the possible effects that stilbestrol pellet-implanted chickens might have, whereas their work was concerned with ingestion of a different substance entirely, is that not correct?

Dr. HINES. Well, I did not criticize the experiments at all. I have criticized——

Mr. GOTTLIEB. The carrying over.

Dr. HINES (continuing). The carrying over, where the carrying over is obviously irrelevant.

Mr. GOTTLIEB. That is fine.

Now, tell me, Doctor, have you conducted any tests in which you have fed the flesh of pellet-implanted chickens to any group of human being over a long period of time?

Dr. HINES. I am not aware of any such work.

Mr. GOTTLIEB. Don't you think that is rather important?

Dr. HINES. I don't think it is necessary because of these results that have been obtained by several laboratories that the quantities of estrogen in those tissues are insignificant.

Mr. GOTTLIEB. Doctor, I believe in your statement you pointed out that it is very possible that small amounts of diethylstilbestrol administered over a continuous period of time may be more potent or may exert greater physiological effects than large doses given intermittently, is that not so?

Dr. HINES. What do you mean by small doses?

Mr. GOTTLIEB. I ask you, what did you mean by small doses?

Dr. HINES. I meant doses in the order of a quarter or one-half of a milligram. I do not mean doses of the order of a few micrograms.

Mr. GOTTLIEB. Do you know of any work anywhere where doses in the order of a few micrograms have been administered to human beings over a long period of time on a controlled experimental basis?

Dr. HINES. No, I do not, but I think we have the evidence from our daily experience. We know that there are small quantities of estrogen in a great many kinds of foods and we know, therefore, that people are taking those in all the time and have been for generations.

I do not know exactly how many micrograms, and it probably varies from time to time, but from what we know about the amount of estrogen that is contained in food and from what we know about food consumption in general, I think we can say that without any question people do take those quantities in all the time.

Mr. GOTTLIEB. Well, that is true, Doctor, and that has been testified to by others before this committee. You state in your original statement that stilbestrol is a powerful substance, is that not so?

Dr. HINES. That is right.

Mr. GOTTLIEB. If we are taking an unknown quantity of estrogen in our foods where it occurs naturally, and if this is a powerful substance, don't you think we ought to be careful about artificially adding to that quantity in our daily food?

Dr. HINES. When you say it is a powerful substance, it is, and diethylstilbestrol may be two or three times as powerful as the same quantity of estrogen, that is true. But the means of assaying all these tissues for diethylstilbestrol—they are biological assays, and they are a measure then of the potency.

Mr. GOTTLIEB. What do you mean by a biological assay?

Dr. HINES. The standard assay is made with a group of female rats or mice from which the ovaries have been removed when they are very small. Then they are kept under uniform conditions, and they are given by injection a certain amount of estrogen every week to keep them in a constant state of responsiveness because if they go without it for a time their responsiveness diminishes.

Then, some of the animals are given test injections of a standard material of known content, and others of the group are given injections of the unknown substance that you are assaying, and then over a period of time they take smears from the vaginas of these mice, and those are put on a slide, and they are stained and they are examined under the microscope to see what kind of cells there are, so they compare then the response of the unknown to the response of the known.

Mr. GOTTLIEB. I take it then what you are getting at is a physiological response of the mouse or the rat, is that not so?

Dr. HINES. That is right.

Mr. GOTTLIEB. Doctor, aren't you running the risk of doing what you have complained about in your statement, something about being very careful about carrying over to human beings of observations made on experimental animals? In fact, you state:

I cannot overemphasize the fallacies inherent in the effort to apply directly to man the results of animal experiments in the field of hormones.

Dr. HINES. That is perfectly true, and I do not know of anybody who is satisfied with the biological assay of estrogens, but it just happens it is the only kind of measure that we have for small quantities, and interpreting the results we have to allow for a considerable discrepancy. I think the people in the Food and Drug Administration who have had experience with this will readily agree with me.

Mr. GOTTLIEB. It is a very rough measure, is it not?

Dr. HINES. That is right; it is a very rough measure.

Mr. GOTTLIEB. And the assays which are appended to your paper here are very rough assays because the method has not been developed to refine it?

Dr. HINES. That is right. As to the nature of the method, I don't think it can be refined further. The difficulties are inherent in the method; but nevertheless the assays give us an idea of the order—they tell us whether it is micrograms or milligrams, for instance. But it would be very foolish to think that they do anything more than that.

Mr. GOTTLIEB. Doctor, if, as you have testified, ingesting the flesh of chickens treated with stilbestrol or even ingesting the pellets is a pretty neutral sort of situation, which may not do anybody any particular good and on the other hand may not do anybody any particular harm, are you in favor of lifting whatever restrictions there may be now upon the stilbestrol pellets, or their implantation?

Dr. HINES. What restrictions are there now?

Mr. GOTTLIEB. They have to be implanted in the base of the skull. I understand that only one should be implanted in ordinary chickens; they should not be marketed prior to 4 to 6 weeks after implantation. Aren't those restrictions?

Dr. HINES. Yes.

Mr. GOTTLIEB. You think those could be very well eliminated and there would be no particular problem?

Dr. HINES. No, I think it is just as well to keep that.

Mr. GOTTLIEB. Why?

Dr. HINES. Because even though these things do not do any harm, there may possibly be somebody who lives on chicken necks.

Mr. GOTTLIEB. There may be such a person?

Dr. HINES. There might be.

Mr. GOTTLIEB. Are you familiar, Doctor, with the fact that there is experimentation going on right now in the use of stilbestrol on other meat animals, which we eat?

Dr. HINES. I have heard that there is such experimentation going on.

Mr. GOTTLIEB. You are aware of that?

Dr. HINES. Yes.

Mr. GOTTLIEB. Presumably they expect to produce the same results in other meat animals as they do in chickens, namely a heavier, fatter animal, is that not so?

Dr. HINES. I would presume that was their purpose.

Mr. GOTTLIEB. Do you think there is, in your opinion, any danger at all to the public if all the meat that we eat, including chickens, were being treated with pellets of stilbestrol?

Dr. HINES. That depends entirely on how much accumulates in the tissues of these particular species that are under consideration.

Mr. GOTTLIEB. You do not think that the addition of any amount of estrogens over and above what we are getting in our natural foods today and over and above what we may be getting in poultry today would be particularly harmful, if it were small?

Dr. HINES. If it were small, I would not say it was harmful, no. But before I gave an opinion on any other species I would want to know something about the assays there.

Mr. GOTTLIEB. You know there is such a possibility that all our meat animals will be treated with stilbestrol, you do know that?

Dr. HINES. Yes.

Mr. GOTTLIEB. Doctor, do you think that the regulations limiting or restricting the use of stilbestrol, for example, the method of implantation, is necessary to keep abuses out of the practice?

Dr. HINES. Well, I do not know quite what you mean by abuses. What would you envision?

Mr. GOTTLIEB. Let us take the chicken situation in New York, four pellets implanted anywhere in the chicken other than the base of the skull, sold to the consumer with perhaps 4, 5, 8 milligrams of stilbestrol unabsorbed in the pellet.

Dr. HINES. Well, I think those people who do that are wasting their material because, as I understand it, one pellet does all that can be done for the chicken.

Mr. GOTTLIEB. Well, the fact is that they do it, whether they are wasting it or not, and it is getting out on the market. Do you think we ought to keep those regulations in force?

Dr. HINES. I think on general principles it would be a good idea.

Mr. GOTTLIEB. Do you think it might be a good idea, perhaps, to license poultry raisers who desire to implant stilbestrol pellets to make sure that they do not abuse that practice?

Dr. HINES. Well, that is something I would not know about.

Mr. GOTTLIEB. Doctor, I have here a publication from Nature magazine, February 24, 1951. Are you familiar with that magazine?

Dr. HINES. Yes.

Mr. GOTTLIEB. It is a reputable scientific magazine?

Dr. HINES. Yes, British.

Mr. GOTTLIEB. The article is entitled "Toxicity of Estrogens," and it is reported on by T. Nichol and I. D. Helmy of the department of anatomy, Kings College, London.

Now, they conducted several experiments with laboratory animals, using synthetic and natural estrogens, and stilbestrol was one of them. Just let me read you one of the conclusions. I quote:

> It was found that the synthetic estrogens were more toxic in small than in large daily doses. In the animals treated with stilbestrol the mortality was higher in those who received a daily dose of one-tenth of a milligram than in those who received a daily dose of 1 to 5 milligrams.

Is that consistent with your observations as far as the human being is concerned?

Dr. HINES. It has no relation to the observations on human beings.

Mr. GOTTLIEB. You do not believe that smaller quantities of stilbestrol taken continuously for a long period of time are any more potent or produce any greater physiological effects than single large doses given intermittently?

Dr. HINES. Now, that is a different matter. Could I just see that for a minute?

Mr. GOTTLIEB. Well, would you answer the question?

Dr. HINES. Well, the two are not the same questions. In human beings, certainly, you can pick small doses and give them continuously, and get more effect than you can giving large doses intermittently. That is the point I have been trying to make here. But that does not mean that small doses given continuously have more of an effect than large doses given continuously. There is no evidence that small doses given continuously will have more effect than large doses given continuously.

Mr. GOTTLIEB. Now, Doctor, on page 2 of your statement you stated:

> We submitted to the Food and Drug Administration reports covering more than 8,000 patients who had received the new drug.

By that you mean stilbestrol?

Dr. HINES. That is right.

Mr. GOTTLIEB (reading):

> Eighteen hundred of these patients have received it more or less continuously over periods ranging from 6 months to 2 years.

Now, you submitted this information to the Food and Drug Administration for what purpose?

Dr. HINES. To establish to the Food and Drug Administration that deithylstilbestrol was safe for general use by physicians.

Mr. GOTTLIEB. For clinical use?

Dr. HINES. That is right.

Mr. GOTTLIEB. Not for pellet implantation in chickens?

Dr. HINES. No, this has nothing to do with that.

Mr. GOTTLIEB. These patients were all under the supervision of a physician, were they not?

Dr. HINES. Yes, they were.

Mr. GOTTLIEB. And the estrogen was administered under the supervision of a physician?

Dr. HINES. That is right.

Mr. GOTTLIEB. There was something wrong with these people?

Dr. HINES. Well, I do not know that you can say there was anything wrong with them. The menopause is a physiological state. I do not think you can say there was anything wrong with a woman going through the menopause, and probably half of these people were being treated for menopausal symptoms.

Mr. GOTTLIEB. Dr. Greenblatt testified that by far the largest use for diethylstilbestrol was in the treatment of menopausal symptoms in women.

Dr. HINES. That is true; yes.

Mr. GOTTLIEB. And he indicated that the menopausal difficulty was due to a deficiency of estrogen in the system.

Dr. HINES. Well, now, did he actually say that?

Mr. GOTTLIEB. Is that a true statement?

Dr. HINES. No; nobody knows the cause of menopausal symptoms, and nobody knows the mechanism by which they are relieved by estrogen.

Mr. GOTTLIEB. But they are relieved by estrogen?

Dr. HINES. They can be; yes.

Mr. GOTTLIEB. And are estrogens the only things that will relieve it?

Dr. HINES. No.

Mr. GOTTLIEB. What else will?

Dr. HINES. Sometimes testosterone will on some patients, and in some women a little sympathetic talk will relieve them.

Mr. HORAN. May I interpose there, counsel? How about ergot? That is administered sometimes in connection with——

Dr. HINES. With childbirth.

Mr. HORAN. Yes; and with disorders of the female, particularly.

Dr. HINES. I do not think it is used in that way very much any more. It is pretty much now limited to childbirth and the treatment of migraine.

Mr. HORAN. Yes. I know it is administered for migraine, and it is quite effective. But it is my understanding that it had some effect on the female organs.

Dr. HINES. Well, it will promote contraction of the uterus and sometimes if a woman is going to menstruate in a day or two it will hasten the appearance of that menstruation by contracting the uterus and squeezing it down.

Mr. HORAN. Thank you.

Dr. HINES. I think the use of ergot for that purpose by the medical profession is rapidly declining.

Mr. HORAN. Yes, but it has in the past been recognized as a standard and safe drug.

Dr. HINES. Yes.

Mr. HORAN. Administered under the direction of physicians.

Dr. HINES. That is right.

Mr. GOTTLIEB. Doctor, at page 460 of our 1951 hearings Dr. Greenblatt testified:

> In our clinic we have accustomed ourselves to the use of the smaller doses, 0.1 milligram three times a day. In occasional cases we have gone to 0.25 milligram three times a day, and in other occasional cases even up to 1 milligram a day. The indications are the need for replacement due to a deficiency in the production of estrogen hormones. It does not have to be stilbestrol; other estrogens or estrogen-like substances may be used.

You disagree with Dr. Greenblatt?

Dr. HINES. Well, I am not sure that in that Dr. Greenblatt meant to say that it was a deficiency of estrogen that caused the symptoms.

Now, to be sure, women who are in the menopause do have a deficiency of estrogen, there is no doubt about that, but there is no evidence that I am aware of that indicates that that is the cause of the symptoms.

Mr. GOTTLIEB. By definition if a woman is deficient in estrogen, then the only thing that will take care of the problem is to provide the estrogen; is that not so?

Dr. HINES. Well, if you are going to restore all of the things that are due to the deficiency, yes, that is the only way you can do it.

Mr. GOTTLIEB. The point I am getting at is in these 8,000 patients who had received this new drug for menopausal problems, isn't it true that these women had a deficiency of the particular thing which was being administered?

Dr. HINES. No. Those women who had menopausal symptoms, most of them had a deficiency, yes; but actually not all of them do have, not all women who have menopausal symptoms have a deficiency, and then diethylstilbestrol is used in many conditions in which there is no deficiency of estrogen at all.

Mr. GOTTLIEB. What are the contra-indications to estrogen therapy, Doctor?

Dr. HINES. Well, those are changing. I would say that in the past it was considered, for instance, that any woman who had a family history of cancer of the breast or cancer of the uterus was safer if she did not receive estrogen.

That was before anybody knew that the administration of estrogen could result in the regression of cancer of the breast. I am not sure now that that is a valid contra-indication. I think there is some question about that.

Now, of course, what they are talking about there is quantities of estrogen of certainly one-tenth of a milligram up, and it refers to continued administration.

Mr. GOTTLIEB. Doctor, are you saying that when a woman has a cancer the indicated therapy is estrogen?

Dr. HINES. Yes, in some instances; yes, definitely.

Mr. GOTTLIEB. In some instances?

Dr. HINES. Yes.

Mr. GOTTLIEB. Is it advisable for a physician before he prescribes estrogen to make certain examinations of the patient, physical or otherwise?

Dr. HINES. It is customary to do that.

Mr. GOTTLIEB. Why?

Dr. HINES. So that he knows what the patient's condition is before he starts the estrogen.

Mr. GOTTLIEB. So that he can keep tabs on whether, perhaps, the cancer is becoming aggravated or accelerated or if no cancer had existed that no cancer is coming into being; is that not correct?

Dr. HINES. Yes.

Mr. GOTTLIEB. And that there is, at least in the minds of many reputable men, a feeling that there may be some association between estrogens and cancer in some way, whether it is by acceleration of tissue growth or actual production?

Dr. HINES. There has been some feeling to that effect; that is right.

Mr. GOTTLIEB. We really do not know, do we, one way or the other on that?

Dr. HINES. Well, we can say this: That estrogens in potent form have been available for 20 years now. Diethylstilbestrol has been available for 12, and it is perfectly true that there are certain cases of cancer of the breast and cancer of the uterus that have been discovered, and have apparently developed, during periods of estrogen therapy.

Now, of course, that does not prove that the estrogen caused the growth in that particular instance. The only way that you can come to any conclusion about that is by having a large series of paired cases in which pairs are absolutely parallel with respect to family history and general status, and treat half of them with estrogen and have the other half not treated with estrogen and see what the difference is in the incidence.

Mr. GOTTLIEB. That has not been done yet?

Dr. HINES. That has not been done, and it is not a very feasible thing to do in a civilization like ours.

Mr. GOTTLIEB. Is it not a fact that the current edition of the AMA New and Nonofficial Remedies indicates that family history of cancer may contraindicate estrogen therapy?

Dr. HINES. I think it is. But, as you know, it sometimes takes a long time for something that is undergoing change to receive official recognition.

Mr. GOTTLIEB. Doctor, do you know that X-ray is also used to fight cancer?

Dr. HINES. Yes.

Mr. GOTTLIEB. Is it not a fact that X-ray also produces cancer, and that is a recognized fact?

Dr. HINES. Oh, yes, it can.

Mr. GOTTLIEB. We do not go around exposing ourselves unnecessarily to X-ray for that reason; is that not so?

Dr. HINES. I would say rather that we limit the amount of exposure.

Mr. GOTTLIEB. Exactly; and the people who operate X-ray machines get behind lead barriers so that they do not get too much of it?

Dr. HINES. That is right.

Mr. GOTTLIEB. In your opinion should there be any different yardsick for safety used in evaluating a substance which is proposed for use as a drug for therapeutic purposes under the supervision of a physician and a substance which is proposed for use in a food?

Dr. HINES. Well, I do not know quite what you mean by that.

Mr. GOTTLIEB. Would you apply any stricter standards for a chemical which is being proposed for use generally in food than you would for a chemical which is being used by physicians for therapeutic purposes in their practice?

Dr. HINES. I think that depends on the use that is going to be made of it.

Mr. GOTTLIEB. Let us take stilbestrol.

Dr. HINES. All right.

Mr. GOTTLIEB. Would you answer the question with respect to stilbestrol?

Dr. HINES. Certainly, the amounts of stilbestrol that are going to be found in the livers and flesh of the animals, I would say, have been demonstrated to be so small that they can be disregarded. I do not see that it can do any harm at all.

Now, as to the residues of pellets, if they are taken intermittently, there is no evidence that they are going to do harm.

Mr. GOTTLIEB. But, Doctor, you have just stated that no such experiments have been carried out, that is, the feeding of the flesh of these animals to people, so how can you say there is no evidence? There has been no attempt made to get the evidence; is that not so?

Dr. HINES. I think we have the evidence.

Mr. GOTTLIEB. You have an experiment in which human beings have been fed the flesh of stilbestrol-treated chickens over long periods of time?

Dr. HINES. No; nature has performed an experiment for us which I think meets the requirement.

Mr. GOTTLIEB. But you are adding an additional amount to the diet, are you not, over and above what nature has added?

Dr. HINES. No, not necessarily, not in the livers and not in the livers and flesh, because the amounts that have been found in there are so small, if there is any, that they can hardly be measured. They fall within the physiological range. Now, we do not know exactly how much estrogen is produced in men and women; there is no way of measuring that. We do know how much is excreted, and there is a considerable normal variation. Some people may excrete two or three times as much estrogen as others, and that is all considered to be in the normal range.

Mr. GOTTLIEB. Do you know what hyperestrinism is, Doctor?

Dr. HINES. Definitely.

Mr. GOTTLIEB. What is it?

Dr. HINES. It is a condition in which there is too much estrogen present.

Mr. GOTTLIEB. This condition may be present in human beings, is that not so?

Dr. HINES. Yes.

Mr. GOTTLIEB. Do you know that this condition of hyperestrinism is getting a lot of study these days in an attempt to determine whether that may be one of the causes of cancer in human beings today?

Dr. HINES. It may be possibly one of the factors.

Mr. GOTTLIEB. So the fact that something occurs naturally within or without our bodies does not necessarily mean that it is particularly good for us.

Dr. HINES. No, that is quite right, but that is not what I am talking about. Hyperestrinism is a result of constant overactivity of the ovaries or the presence of estrogen-producing tumors in men, and it occurs only when there is a constant production of estrogen, when the cycle has been interfered with. Normally there is a period of about a week that begins a few days before the menstrual period

when the woman has practically no circulating estrogen and her organs and tissues get a rest from estrogen, and then estrogen is present the other 3 weeks. Hyperestrinism occurs in connection with a constant production of estrogen.

Now, what I was trying to make clear before was that there was a considerable variation in the normal excretion of estrogen and, therefore, I think one is entitled to conclude that there is probably a considerable difference in the amount of circulating estrogen in different people.

Now, a chicken is ordinarily substituted for other meat as food, and if you do not eat the chicken you are going to eat some meat. In other words, if you do not eat one kind of food you are going to eat another, so that the practical difference, I think we can say, is inconsequential, whether we get a certain amount of estrogen, if we get any at all, out of a beefsteak or whether we get an amount that is in many instances too small to measure out of the carcass of a treated chicken. I think we can say definitely from the experience of the human race and from the assays of the amount of estrogen that is in these chicken livers and chicken carcasses, that the intake will still fall within the natural range.

Mr. GOTTLIEB. Doctor, there has been testimony before this committee that there are several cosmetic preparations on the market, oils, lotions, and creams, each of which contains 20,000 international units of estrogen for a 30-day supply.

Now, these estrogenic cosmetic preparations are being sold to the women of this country with the recommendation that these preparations, one or more of them, be applied to their scalps, their faces, necks, throats, shoulders, arms, hands, and in some cases the legs.

The mode of application is such that all of these preparations may remain on a woman's body 24 hours a day every day of the year.

It has also been testified that the absorption rate of these creams, oils, and lotions may be from 20 to 50 percent.

Do you think that there is any possible hazard to a woman who uses these cosmetics, as I have indicated, over long periods of time, and consumes stilbestrol-treated poultry, and other foods in which natural estrogens may be present?

Dr. HINES. Well, I would say this: That the flesh and the livers of these stilbestrol-treated birds would not add measurably to the total intake.

Mr. GOTTLIEB. Our committee, Doctor, is interested in the whole picture. We have to consider all the sources of estrogen, both in foods and in cosmetics, as well; and, as an expert in this field, I would like your opinion as to whether this sort of use might be dangerous.

Dr. HINES. Well, I would say that the continuous application of those concentrations of estrogen to the skin would be undesirable.

Mr. GOTTLIEB. And anything that added to it might make it worse; would you say that?

Dr. HINES. Well, that depends on how much you add.

Mr. GOTTLIEB. Well, in the quantities that we might get from chickens——

Dr. HINES. No, I do not.

Mr. GOTTLIEB (continuing). Ingesting pellets.

Dr. HINES. I am assuming that the pellet is an intermittent thing. I am not assuming that somebody is going to take the residue of a number of pellets every day, day in and day out.

Mr. GOTTLIEB. Well, in addition to the cosmetic use that you indicated might be dangerous. Would the addition of stilbestrol-treated poultry help these women in any way?

Dr. HINES. No; but I do not think it would harm them. It would not make any difference.

Mr. GOTTLIEB. Would you be at all concerned if, perhaps, a little more were added, if, for example, all of the meat animals that we ate had some additional amount of stilbestrol?

Dr. HINES. Well, that depends on how much they would have. If they have the same concentrations as there seem to be in the chickens, I would say it makes no difference.

Mr. GOTTLIEB. Doctor, on page 29 of your statement you say that a man can do himself serious damage by drinking too much water or putting too much salt in his food.

Dr. HINES. That is right.

Mr. GOTTLIEB. Or doing any one of a number of things which, under most circumstances, are normal and harmless.

Are you equating water to stilbestrol so far as danger or hazard is concerned?

Dr. HINES. No.

Mr. GOTTLIEB. You would not say that water is a powerful substance in the same sense that you have indicated that diethylstilbestrol is?

Dr. HINES. Well, you have to take more of it, but aside from that quantitative difference, I think water is a very powerful substance.

Mr. GOTTLIEB. Is there anything which is not a very powerful substance in the same sense that you are considering water?

Dr. HINES. Well, that I do not know.

Mr. JONES. Doctor, we thank you very much for appearing here, and I express the appreciation of the committee for your appearance.

The committee will stand in adjournment until the call of the chairman.

(Whereupon, at 4 p. m., the committee adjourned, subject to call.)

CHEMICALS IN FOODS AND COSMETICS

WEDNESDAY, FEBRUARY 13, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE USE
OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess., continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 10 o'clock a. m., in room 445, Old House Office Building, Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney, of New York; Abernethy, of Mississippi; and McDonough, of California.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will be in order.

Mr. Kleinfeld.

Mr. KLEINFELD. Mr. Chairman, before going into the question of the fluoridation of water, you will recall that last year Dr. McCay, of Cornell University, as part of his statement, referred to the allegedly deleterious effects of cola beverages upon teeth.

I have two statements here, one by Dr. James Nuckolls, of the University of California, and one by Dr. John Haldi, of Emory University, which set forth a contrary point of view. I suggest that these be made part of our record.

The CHAIRMAN. Without objection, it is so ordered.

(The two statements referred to are as follows:)

UNIVERSITY OF CALIFORNIA,
COLLEGE OF DENTISTRY,
San Francisco, Calif., January 17, 1952.

Hon. JAMES J. DELANEY,
House of Representatives, Congress of the United States,
House Office Building, Washington, D. C.

DEAR MR. DELANEY: I have noted a number of articles which have appeared in the public press, and more recently in the New York Dental Journal, which refer to a testimony given by Clive M. McCay, of Cornell University, before your committee which is set up to investigate the use of chemicals in food products. I have also had the opportunity of reviewing the original testimony of Dr. McCay and the comments and questions of your committee regarding the subject of acid erosion of the teeth which is produced in experimental animals when they continuously consume solutions which have an acidity that will cause a loss of the enamel.

My interest in the processes which have to do with the development and disintegration of teeth is of long standing, since I have served continuously on the staff of the college of dentistry as a researcher and teacher for more than 25 years. At the present time, I hold a professorial rank in the sections of oral histology and oral pathology and the chairmanship of the division of pre-

clinical sciences in the college of dentistry. My bibliographical data is best referred to in Who's Who on the Pacific coast, 1951 edition, and in World Bibliography, 1948 edition.

I am taking the liberty of writing you because I fear that certain misinterpretations might be placed on the testimony with regard to tooth erosion.

In the first instance, it should be made clear that the process of enamel erosion is in no way synonymous to the disease of tooth decay. In fact, the available scientific evidence does not relate one to the other. The disease of dental decay or caries of the teeth is the result of bacteria acting on the structures of the teeth which produce a characteristic picture when studied under the microscope. On the other hand, tooth erosion consists of a progressive dissolution of the enamel and underlying dentin. This is brought about by the action of acid solutions on the teeth. The gross and microscopic picture of acid erosion of the enamel is completely different from that of dental caries. The eroded areas are for the greater part smooth, hard, and slick, and may not show evidence of bacterial penetration into the deeper parts of the tooth.

Teeth can also be worn away in specific areas by means other than acid. It is generally believed that the most common ways this can be brought about are by the use of the tooth brush with very hard bristles, or a wearing away of the grinding surfaces by coarse, gritty foods. This localized and partial destruction of the tooth is referred to as abrasion to distinguish it from erosion caused by acid. Clinically, it is extremely difficult to tell whether we are dealing with erosion or abrasion, since the clinical pictures of the end result are very similar. In my opinion, it is very seldom that we have simple erosion in human teeth but that it is usually complicated by other factors.

In making a differential diagnosis between erosion and abrasion, it must be borne in mind that the clinical picture of both conditions may appear to be similar. Therefore, in distinguishing between the two lesions, one must consider the food habits as well as the abrasive habits and the occupational habits of the patient. From my observations, based on considerable clinical experience, the smooth, hard V-shaped areas which occur predominantly at the necks of certain teeth are primarily the result of mechanical abrasion. This is also true of teeth which have been displaced to one side of the dental arch so that they receive the brunt of tooth brushing. There are also conditions when undoubtedly these lesions are caused both by erosion and abrasion. However, the establishment of the chief causative factor would be most difficult.

In the testimony on tooth erosion before your committee, it was shown that acid beverages produce erosion in rats' teeth. From this testimony, some might be inclined to conclude that human consumption of acid beverages, and this would include some 12 or more naturally occurring fruit juices which have an acid reaction as well as carbonated beverages, can be expected to cause erosion in human teeth.

It is important to be aware of the fact that in McCay's testimony there was no direct evidence whatsoever to show that this is the case. There were no experimental observations made on the live human tooth. It is also important to keep in mind that there are distinct differences between rats' teeth and human teeth and between the mode and habits of drinking by the rat and by man. If the ordinary acid beverages and acid fruit juices, which are widely consumed by man, cause the destruction of human teeth as you might be led to believe from the testimony in question, a clear-cut erosion of human teeth would be commonplace. This, however, is not the case. In my 20 years of part-time practice in a medical-dental group, I can recall only three cases in which I was absolutely sure that I was dealing with acid erosion and not abrasion. These case histories included one individual who regurgitated following meals and had erosion on the tongue side of the upper front teeth; another had a condition know as achlorhydria and as the result, consumed hydrochloric acid without taking the necessary precautions of protecting the teeth; and another consumed excessive amounts of fresh citrus fruit juices.

As the result of a wide clinical and experimental background, it seems to me that the detrimental effects resulting from a reasonable consumption of beverages as well as naturally occurring fruit juices which have an acid reaction have not been shown to produce demonstrable pathological effects on the teeth of the human. Neither does the acidity seem to influence the extension of dental decay. On the other hand, if one is to condemn all beverages with an acid reaction, one must also group many of the naturally occurring fruit juices in a similar category and on a basis which, at the present time, is not supported by adequate scientific evidence.

Hoping that this communication, in part, may serve to throw additional light on a highly controversial subject, I remain

Sincerely yours,

JAMES NUCKOLLS.

P. S.—I am enclosing a documented manuscript for your perusal, which I have recently prepared for publication.

EMORY UNIVERSITY,
SCHOOL OF DENTISTRY,
Emory University, Ga., January 17, 1952.

Hon. JAMES J. DELANEY,
House of Representatives, Congress of the United States,
House Office Building, Washington, D. C.

DEAR MR. DELANEY: With your permission I should like to make a few comments on the statements made by Dr. Clive McCay, of Cornell University, on the subject of tooth erosion before your select committee to investigate the use of chemicals in food. I have hesitated for a long time to write to you although I have been quite disturbed over the possibility that those who heard or will read Dr. McCay's testimony may be inclined to misinterpret certain laboratory findings. In view of the fact that the hearings before the committee have been published and Dr. McCay's testimony thereby given wide distribution, I have finally decided to write to you in the interests of clear thinking on this subject.

You will understand my concern in this matter when I tell you that I am professor of physiology in one of our leading dental schools and that I have been engaged for several years in a study of tooth erosion, and I am still carrying on research investigations on this problem. I received the Ph. D. degree in physiology at the University of Cincinnati in 1923 and since then I have been engaged in teaching and research. In 1948 I was appointed professor of physiology and chairman of the department of physiology in the Emory University Dental School, having served for 15 years previously as assistant and associate professor in the medical school in the same univerity. Prior to my coming to Emory University, I was instructor and later assistant professor in the department of physiology in the medical school at the University of Michigan. In 1929 I was made a member of the American Physiological Society and am still a member of that society. Much of my research has been concerned with problems of metabolism and nutrition. I have published about 40 papers in scientific journals, principally in the American Journal of Physiology and the Journal of Nutrition.

Several years ago my associate, Mr. Winfrey Wynn, and I published a paper entitled "The Erosive Action of Various Fruit Juices on the Lower Molar Teeth of the Albino Rat" (Jour. Nutr. 35. 489, 1948). In this study we found that marked erosion could be produced in the lower molar teeth of albino rats by allowing them to drink such fruit juices as grapefruit, grape, apple, pineapple, orange, and prune. The teeth were also eroded to some extent by tomato juice.

When we wrote this paper we were a bit fearful that someone might uncritically apply these findings on the rats' teeth to man, and in the popular press, or elsewhere, denounce the human consumption of fruit juices on the ground that they might erode the teeth. This would indeed be both unfortunate and deplorable; first, because fruit juices have become a part of our way of life, and secondly, because the fruit-juice industry is an important segment of our American economy.

I should like to make it clear that tooth erosion is not the same thing as dental caries or tooth decay. Many laymen may be confused on this point. Tooth decay, as the name signifies, involves a "decay" process. This is what gives the carious areas the familiar brownish color. Tooth erosion which is far less common than tooth decay is something entirely different. It consists of a dissolution, which frequently appears as a cupping out, of areas of enamel on the outer surface of the tooth.

It is this loss of enamel and not tooth decay which was observed in our experiments on rats that were allowed to drink fruit juices. There is not much in the literature on the extent to which erosion occurs in human teeth. Certainly, we did not want anyone to assume that our experiment on rats proved, or even indicated, that the ordinary consumption of fruit juices caused erosion in human teeth, even though erosion in many instances may not have serious consequences.

We therefore issued a warning to this effect in the concluding paragraph of our paper. This admonition was based on a number of considerations:

1. The amount of fruit juices ingested by the animals in our experiment was relatively much greater on the basis of body weight than what might be assumed to be the average human consumption.

2. The drinking mechanism in the rat is different from that in man. The rat laps its fluid and it is not improbable that the fluid in passing through the mouth may be in contact with the teeth longer than in the human mouth.

3. At the present time we have only limited knowledge on the difference in the chemical composition, crystalline structure, and solubility in acid of the rats' teeth and human teeth, but unquestionably such differences do exist.

4. On human teeth there is formed a thin covering composed of mucin from the saliva and other material. This is usually referred to as a plaque. It may be removed by brushing the teeth, but it is formed again in a relatively short time. This plaque, in the opinion of some investigators, may serve as a protective covering to prevent contact of acid with the surface of the tooth. As far as I know, no one has shown that there is a similar plaque formed on rats' teeth.

5. In the mouth, saliva serves the purpose of cleansing the teeth and at the same time neutralizing acid. This latter property is referred to as the buffering power of saliva. At the present we have no information on the rate of flow of saliva and the buffering capacity of saliva in the rat as compared with man.

In view of these considerations, it is quite obvious that it would be unwise and unreasonable to apply the findings on rats' teeth under experimental conditions to human teeth without further extensive studies on man under similar conditions.

In Dr. McCay's testimony your committee was told that rats' teeth were eroded when the rats were given a cola beverage to drink. The implication seems to have been that the consumption of cola beverages constitutes a public health hazard because they might erode human teeth.

If we should go along with this kind of reasoning and accept this conclusion, then to be consistent, we would have to conclude from our studies that fruit juices and other acid-containing foods should be avoided if we want to protect our teeth. This conclusion I refuse to accept and I should like to state here with all the emphasis at my command, that at the present time we have no evidence from the study of human teeth that erosion is caused by the ordinary consumption of fruit juices or other acid-containing beverages, such as the cola beverages.

Many natural foods contain acid, some of them 20 to 100 times as much as the cola beverages. For example, lemon juice contains approximately 6.4 percent acid; orange, 1.1 percent; cranberry, 2.1 percent; plum, 2.5 percent; apple, 0.75–1.00 percent; prune, 1.4 percent. Even lima beans contain 0.8 percent acid which is approximately 15 times the amount of acid in the cola beverage studied by Dr. McCay. The concentration of acid in this beverage is about fifty-five thousandths of 1 percent (0.055 percent).

There is acid in other foods. Vinegar contains acetic acid and this acid is used not only for making pickles, but also in salad dressings, etc. Citric acid is present in the hard candies which are sold in grocery stores and drug stores in every city. As a matter of fact, the citrate ion which is also present in citrus fruits has been found by Drs. F. J. McClure and S. J. Ruzicka at the National Institutes of Health to produce erosion in rats' teeth even in a neutral or slightly alkaline solution. (J. Dent. Res. 25: 1, 1946.)

In view of the large daily consumption of fruit juices and the cola beverages, we could reasonably expect to find relatively few teeth that had not been dissolved if fruit juices and the cola beverages have the same destructive action on human teeth as on rats' teeth. Millions of people the world over have been drinking fruit juices or cola beverages, or both, for many years, some of them most of their lives. Yet we know from our own observations—and dentists will bear us out in this—such extensive destruction of teeth by erosion simply has not occurred.

I shall now proceed to show you in the following order that:

1. Although the cola beverages were singled out as a health hazard because they were found to cause erosion in rats' teeth, it is well known that the same experimental results had been obtained with fruit juices;

2. One is not justified in applying findings on rats' teeth to man;

3. Other statements made before your committee in an attempt to prove that cola beverages are destructive to human teeth are definitely misleading.

I. IT IS WELL KNOWN THAT EROSION CAN BE PRODUCED IN RATS' TEETH BY FRUIT JUICES

Dr. McCay must have read our paper on this subject, for he refers to it in one of his publications. He was also acquainted with the work of McClure which has shown that grapefruit juice and cranberry juice cocktail have an erosive action on the molar teeth of the albino rat. (J. Nutr. 26: 251, 1943.)

In fact, Dr. McCay himself with his associates had observed in his laboratory that erosion can be produced by fruit juices. Let me quote the introductory paragraph of a paper he published in 1945. "Tooth erosion is a rather commonly observed but little understood phenomenon. In a few instances it has been pointed out that the acid in fruit juices, soft drinks, and hard candies can be destructive to human teeth; the present authors have recently observed one instance of very severe damage to the teeth of a 32-year-old man apparently resulting from the practice of sucking the juice from two or more oranges per day over a period of 2 years." (Gortner, Jr., R. A., J. S. Restarski, J. G. Bieri and C. M. McCay. Arch. Biochem. 8: 405, 1945.)

In this same paper the authors describe the erosion produced in the teeth of rats that were allowed to drink a synthetic lemonade in common use in the Army and Navy. Animals that had been drinking the lemonade for 30 days had their lower molar teeth dissolved away nearly to the gum line. "After 5 months on the beverage the lower molars were sometimes completely destroyed beyond the level of bifurcation of the roots, so that only isolated roots remained."

In another paper Dr. McCay and his associates showed that acetic acid which is commonly encountered in pickled foods also produced severe erosion in the rats' teeth. In this same study observations were also made on the erosive action of the citrus fruit juices. I should like to present here the following quotation from this paper: "Citrate ion is known to have a strong affinity for calcium and apparently is an additional factor in the tooth decalcifying properties of citrus fruits and juices. Accordingly, the effects of offering a fresh frozen canned orange juice (pH 3.7) to 10 rats was determined. After 1 week, the rats' teeth showed a degree of destruction comparable to that obtained previously with a 0.2 percent citric acid solution * * *. After 2 weeks, severe erosion of the enamel of the mandibular molars was evident." (Bieri, J. G., C. M. McCay, J. S. Restarski and R. A. Gortner, Jr. Arch. Biochem. 11: 33, 1946.)

In view of these published statements it is quite obvious that Dr. McCay was fully aware of the erosive action on rats' teeth produced by fruit juices, vinegar, various other foods containing acids and hard candies which contain citric acid. And yet he singled out the cola beverages and did not mention these other experimental observations when he testified before your committee.

In a paper published in 1949 (J. Nutr. 39: 313, 1949) Dr. McCay took cognizance of our paper and commented that if the amount of fruit juices consumed by our animals were related to body weight it would be equivalent to having a man ingest one-half to one ton of fruit juice during a period of 200 days. We were well aware of this when we published our paper and this was one of the reasons why we cautioned against applying our findings on rats' teeth to man.

In this paper Dr. McCay concentrates on the erosive action of cola beverages on the teeth and in his preoccupation therewith overlooks two important points. One of these is that his own data reveal equal, if not greater, destructive action of certain fruit acids on the rats' teeth; the other is that the same kind of calculations on the basis of body weight should be applied to his experiments as to ours in relating his observations on the rat to man.

In this experiment he sought to show that a brief exposure to acid beverages causes erosion in the teeth of the rat. I quote two statements from this paper:

1. "In the case of the rat, erosion of the molar teeth can be detected after the consumption of 10 milliliters of acid solutions of the same strength used in cola beverages";

2. "Erosion could be detected after three daily feedings of 3 milliliters of 0.23 percent tartaric acid. Similarly, the effects of a single ingestion of 2, 3 or 5 milliliters of 0.58 percent citric acid could be observed."

Two points invite attention. One is that erosion was produced by smaller amounts of the tartaric and citric acid solution than with the cola beverage. The other is that tartaric acid occurs naturally in grapes, citric acid in oranges, lemons, and grapefruit.

The concentration of tartaric acid in canned grape juice is about 1 percent, which is four time the concentration that Dr. McCay used in producing erosion in the rats' teeth. The concentration of citric acid in canned orange juice is around

0.9 percent, and in grapefruit juice about 1.3 percent which is twice the concentration Dr. McCay used when he obtained erosion with a single ingestion of 2, 3, or 5 milliliters.

It was not stated whether the erosion was much or little or how long it took the animals to drink 10 or 5 cubic centimeters of the cola beverages. I can tell you from my own laboratory studies that if there was any erosion it could have been seen only through a microscope. I can also tell you from my own observations that if you offer 10 or 5 cubic centimeters of a cola beverage to rats they will lap it up without stopping.

But all this is beside the point. What I want to show is that apart from differences between the rat and man in the composition of the teeth, manner of drinking, etc., these experiments do not prove that cola beverages or fruit juices cause erosion in human teeth. I shall use the same criteria that Dr. McCay used in his comments on our experiments to which I have referred.

I do not know the size of the rats he used, but let us assume they weighed about a third of a pound. This is a fair sized rat. If they weighed, say half a pound or even more, slight modifications will have to made in our calculations.

If a rat weighing a third of a pound drank 10 cubic centimeters of a cola beverage, that would be equivalent to 30 cubic centimeters per pound of body weight. Applied to a man weighing 150 pounds that would be 4,500 cubic centimeters, which is more than a gallon, or about 25 six-ounce bottles. Applied to a child weighing 50 pounds it would be equivalent to about 8 bottles. Can you conceive of a man or child drinking this amount of a cola beverage at one time?

II. ONE IS NOT JUSTIFIED IN APPLYING FINDINGS ON RATS' TEETH TO MAN

As recently as 1945 Dr. McCay himself recognized this principle. In discussing the effect of acid beverages on the teeth of rats and puppies, he made the statement in the Journal of the American Dental Association, volume 32, page 673, that "These findings on rats and puppies do not justify any definite conclusions with respect to the effects on teeth of acid beverage ingestion by man. The manner of drinking, the relative amount of saliva and its buffer capacity and probably still other factors in the rate at which acid drinks attack the enamel surfaces are different in man from what they are in the animals studied."

These are his own words in 1945. Why he departed from this position when he appeared before your committee is difficult for me to understand. The logic of the situation is the same in 1951 as it was in 1945.

III. OTHER STATEMENTS MADE BEFORE THIS COMMITTEE IN AN ATTEMPT TO PROVE THAT COLA BEVERAGES ARE DESTRUCTIVE TO HUMAN TEETH ARE DEFINITELY MISLEADING

So far I have said nothing about the observations reported before your committee on extracted human teeth immersed in cola beverages. I should like to dismiss these observations as unworthy of serious attention, but since they have been placed in the record it may be advisable to comment on them.

Your committee was told that when human teeth were immersed in a cola beverage they became soft within 2 days and started to dissolve.

I am sure you will agree with me that it is most unreasonable to cite what happens to an extracted tooth when it is immersed in a cola beverage for a period of 2 days. No one holds this beverage or any other kind of beverage in his mouth for 2 days, 1 day, or even 1 hour.

Furthermore—and I wish to state this with emphasis—an extracted tooth placed in an acid beverage does not reflect the environment of that tooth when it was a live tooth in the mouth. In the first place, it is important to note as we have stated before that in the mouth the teeth are covered with a thin coating of mucin and other material which is commonly referred to as a plaque. This plaque, as we have indicated previously, may serve as a protective covering for the teeth and may effectively prevent the contact of acid with the tooth's surface. Secondly, in the mouth there is a continuous flow of saliva. The saliva has a twofold action in protecting the teeth against acid. It washes the acid off the teeth and, at the same time, has a buffering action which, as we have said before, simply means that it contains materials which neutralize acid.

I would also like to call your attention to the fact that an extracted tooth will lose part of its substance when immersed even in distilled water and in many other things besides beverages containing phosphoric acid. We have made numerous observations of this nature in our laboratory.

Here are a few instances of the loss in weight of extracted teeth when immersed in different materials for 72 hours at room temperature: In fresh lemon juice, 35.6 percent; in canned lemon juice, 36.7 percent; in bottled grape juice, 6.2 percent; in dill pickle juice, 7.5 percent; in canned orange juice, 4.4 percent; in apple juice, 4.3 percent; in canned grapefruit juice, 5.5 percent. Under the same conditions the loss in weight in a cola beverage varied from 5.5 to 10.2 percent. We may call to your attention that even in buttermilk there was a loss in weight of the tooth substance within 24 hours.

In these experiments we went a step further and made analyses to determine how much calcium was lost. These analyses showed that calcium constituted a large portion of the total weight loss.

If we were to take the fact that an extracted tooth loses weight when placed in a beverage containing phosphoric acid and reason from this that the beverage should be condemned because of its tooth erosion potentialities, then by identical evidence we are forced to condemn all acid fruit juices and acid-containing foods for having the same potentialities for tooth destruction.

I should now like to comment on the statement made by Dr. McCay before your committee on erosion of monkeys' teeth which he said he produced by cola beverages. Anyone who is concerned with the problem of erosion would naturally be interested in knowing whether under similar experimental conditions the same results would be obtained with monkeys as with rats, since the monkey's teeth and the shape of the monkey's mouth are more nearly like those in man than are the rat's teeth and the rat's mouth.

The general similarity of the contour of the face of the monkey and of man would suggest that the monkey might drink somewhat the way that man does—or at least that you could easily train him to drink that way. That is the impression left with the members of your committee when you were told that "Monkeys that drink in the same manner as men and can be trained to drink from a cup suffer erosion similar to that of rats."

Before we had any laboratory experience with monkeys we thought that they probably would drink the same way as a man. But that is where we made a big mistake. When we first began experimenting with monkeys we soon found that their behavior was quite unpredictable. Perhaps you can teach a monkey to drink from a cup as man does if you start training it when it is very young and exercise a great deal of patience with it, but if you were to place a cup filled with liquid before an ordinary run-of-the-mine laboratory monkey, he would be just as likely to pick it up and throw it at you as to drink it—and more likely to do this if he were not thirsty. If he were thirsty, he might on occasions drink from the cup as a man would, but more often he would put his head into the cup and lap the liquid somewhat as a dog or a rat does. As a matter of fact, we have found—and other laboratory workers will agree with us—that the most satisfactory way to give monkeys water or other fluid is to attach a bottle and a tube to the cage.

What we are interested in knowing is not whether monkeys can be trained to drink out of a cup like men, but whether they were actually trained to do so in Dr. McCay's experiments.

I believe I have read all Dr. McCay's published articles on erosion and in them I can find only one brief reference to actual experiments on monkeys. This is in an article by him and his associates, Bieri, Restarski, and Gortner (Arch. Biochem. 11:33, 1946) entitled "Further Studies on Vivo Tooth Decalcification by Acid Beverages." This article covers about 7½ pages, but only 21 lines are devoted to a description of the method and results of the experiments on monkeys. Only two monkeys were employed in these experiments. I should like to quote here verbatim two sentences from this paper. "To accustom the monkeys to drinking a sweet solution, they were given 160 to 170 milliters daily of a 15 percent sucrose solution from a bottle and tube attached to each cage. After 3 weeks acidic beverages were substituted for the sucrose solution."

Note that it is stated very explicitly that the monkeys were given the solution to drink from a bottle and tube attached. This I cannot reconcile with the statement made before your committee that monkeys drink in the same manner as man. It is not customary for men to drink from a bottle and a tube attached to it.

Of greater interest to us is the statement that these monkey suffered erosion similar to that of rats. In the original paper in which this study was reported we are told that "gross examination of the deciduous teeth revealed that although they were severely worn down by attrition, they generally showed the 'rounding off' of the abraded edges commonly noted in acid ingestion. This was most apparent in comparing the incisors extracted prior to the experiment with those

extracted after the monkeys had been drinking the acid solutions for a month. This comparison also suggested that the phosphoric acid solution caused somewhat greater dissolution of the enamel than did the citric acid beverage."

If you analyze these statements you will recognize that the authors have proved absolutely nothing. The only evidence of erosion which they offer is the rounding off of the edges of the teeth that had been worn down by attrition. It is a gratuitous assumption that this rounding off of the abraded edges of the teeth was brought about by the action of acid. But most important of all there is absolutely no indication whatsoever that there was erosion in the teeth of the monkeys that in the leastwise resembled the erosion seen and reported in rats' teeth. Certainly it does not resemble the erosion that is encountered in human teeth.

In view of the representations made to your committee with regard to experiments on erosion in monkeys' teeth, we thought it would be of sufficient interest to conduct the same kind of experiment in our laboratory. It is a common practice among scientists for one to attempt to confirm for himself the observations made by another.

In this experiment we used six monkeys. One was given a cola beverage as its sole source of fluid. This animal drank around 6 to 8 ounces of the beverage a day. This was equal to about 1 ounce per pound of body weight. On a comparable basis it was equivalent to a man weighing 150 pounds drinking approximately 25 6-ounce bottles per day.

Two of the animals were given 40 cubic centimeters three times a day equal to 4 ounces a day; two others 20 cubic centimeters three times a day, or 2 ounces a day. The sixth animal was used as a control and was given only water to drink. The monkeys given limited amounts of the beverage almost invariably drank it immediately after it was offered to them, usually without pausing.

All the monkeys were fed laboratory chow as much as they would eat. About twice a week they were given fresh vegetables, usually lettuce or carrots.

After they had been kept under these experimental conditions for 120 days, they were sacrificed and the teeth removed and studied under a microscope.

The results of these experiments were most interesting. There was no erosion at all on the molar teeth as was obtained on rats' teeth with the same beverage, nor was there any erosion on the buccal or labial (that is, the outer) surface of any of the teeth. This is where erosion usually occurs in human teeth. The only wearing away of the teeth which might be classified as erosion was on the lingual or inner surface of the central incisors, that is the two middle front teeth. But note this. The same thing was observed in the control monkey. We do not know what caused it, but this much we can say with certainty: It cannot be attributed to the beverage because the control animal was not given any of the beverage.

At the outset of this letter I said that it was written in the interests of clarity of thought on a very important problem. I fear that there may be some who upon reading the testimony on tooth erosion before your committee might not detect the errors in the assumptions and reasoning therein and unwittingly be led to apply the same kind of unsupported interpretation to our experimental studies. Such reasoning would lead to the conclusion that fruit juices cause tooth erosion in man. We wish to go on record as saying that our studies and those of others have not proved that fruit juices or the cola beverages are responsible for tooth erosion in man. For many years investigators have been trying to determine what causes tooth erosion in man, but as yet they have not found the answer. Before this problem is solved it will be necessary that intensive research be conducted on human teeth.

In view of the fact that the testimony on tooth erosion has been incorporated in the record on the hearings before your committee, may I express the hope that those who read this testimony may also be given the opportunity to read the present letter.

Very sincerely yours,

Dr. JOHN HALDI,
Professor of Physiology and Chairman of the Department.

Mr. KLEINFELD. I also have a letter received from the National Cotton Council of America which sets forth the following resolution adopted by that council:

That problems of consumer protection which are raised by the expanding use of various chemicals in the industrial processing of food be met by a policy of insistence that the harmlessness of any chemical be conclusively demonstrated before its use in food is permitted.

I suggest that this letter from the National Cotton Council of America be made a part of the record.

The CHAIRMAN. It is so ordered.

(The letter referred to is as follows:)

NATIONAL COTTON COUNCIL OF AMERICA,
Memphis, Tenn., October 16, 1951.

Hon. JAMES J. DELANEY,
House of Representatives,
Washington, D. C.

DEAR MR. DELANEY: The National Cotton Council has followed with a great deal of interest the hearings of the Select Committee To Investigate the Use of Chemicals in Food Products.

The council is an organization of the entire raw cotton industry, embracing all of the 18 cotton-growing States from coast to coast and includes the six leading raw-cotton interests; namely, farmers, ginners, cottonseed crushers, merchants, warehousemen, and spinners. At the annual meeting of the council last January, a resolution on this subject was unanimously adopted which clearly sets forth the position of this organization.

The resolution is as follows:

"That problems of consumer protection which are raised by the expanding use of various chemicals in the industrial processing of food be met by a policy of insistence that the harmlessness of any chemical be conclusively demonstrated before its use in food is permitted."

We urge that the committee take action along the lines of the council's resolution. The preponderance of evidence adduced by your committee seemed to substantiate this position.

Sincerely yours,

WM. RHEA BLAKE,
Executive Vice President.

Mr. KLEINFELD. You will also recall that the last time we met a statement was inserted in the record which Dr. Newton, the vice president of Swift & Co., had proposed to make before a meeting on chemicals in foods of the Manufacturing Chemists' Association. The Manufacturing Chemists' Association is the trade association, as I understand it, of the manufacturers of chemicals of this country. We have received a letter dated February 5, 1952, from that association, signed by Charles S. Munson, chairman of the board of directors, setting forth the viewpoint of that association on the occurence involving Dr. Newton.

I suggest, in fairness to the association, that that letter be made a part of the record.

The CHAIRMAN. Does not that ask that the entire proceedings——

Mr. KLEINFELD. I was coming to that. I thought first we would put in the letter.

The CHAIRMAN. It is so ordered.

(The letter referred to is as follows:)

MANUFACTURING CHEMISTS' ASSOCIATION, INC.,
Washington 5, D. C., February 5, 1952.

Hon. JAMES J. DELANEY,
Chairman, House Select Committee To Investigate
the Use of Chemicals in Food Products,
House Office Building, Washington 25, D. C.

DEAR MR. CHAIRMAN: On behalf of the Manufacturing Chemists' Association, we respectfully request that the record of your committee be clarified with reference to statements made during the hearings on January 31. We refer particularly to the question and answer period which followed the testimony of Dr. L. G. Cox during which time reference was made to the interindustry conference on chemicals in foods which was sponsored by this association in New York City on January 15. During the discussion referred to, a statement prepared by Dr. R. C. Newton, Swift & Co., was presented by the counsel for your committee

and placed in the record. At the same time a statement was made that opportunity was not given for Dr. Newton's statement to be presented at the interindustry conference.

We would like to point out that Dr. Newton did not request time on the program until after the start of the conference on January 15. At that time he requested an opportunity to read a prepared statement during the discussion period at the end of the meeting. Although time was extremely limited, and there were a number of people in the audience who desired to ask questions and participate in the discussion, Dr. Newton was invited to the platform and devoted approximately 10 minutes to his remarks. Further, his prepared statement was given to the transcript stenographer and has been made a part of the printed record of the meeting which will be included in an early issue of the Food, Drug and Cosmetic Law Journal.

I go into such detail because I think it is necessary to correct the impression left with your committee that Dr. Newton, even though a nonscheduled speaker, was prevented from expressing his views at the interindustry conference. This is not so.

As you know, this interindustry conference had been planned many months in advance and an invitation was extended to you to attend the conference and to have any other members of your committee or your staff attend. The conference was open to anyone who wished to register. There were about 20 invited scheduled speakers, including the Honorable C. W. Crawford, Commissioner of the Food and Drug Administration, Federal Security Agency.

In view of the situation described above, we are very much pleased that Congressman A. L. Miller of your committee suggested that all papers presented at the conference, including Dr. Newton's, be included in the record of the hearings of your committee. We are therefore happy to send you herewith copies of each of the papers presented at the interindustry conference.

If you feel that all of the statements would be too much to include in the record, I should like to suggest that you include at least the following:

The very thoughtful remarks of Commissioner Crawford; the discussion on legislative controls by Dr. F. M. Peters, Jr., vice president of the Quaker Oats Co. of Chicago; and the brief summary of the MCA approach to proposed changes in the present law given by G. J. Williams of the Dow Chemical Co.

Thank you very much for your courtesy.

Very truly yours,

CHARLES S. MUNSON,
Chairman, Board of Directors.

Mr. KLEINFELD. The letter of the Manufacturing Chemists' Association then suggests that perhaps all the papers read at that meeting be made a part of the record, but because of their bulkiness the letter recommends this:

If you feel that all of the statements would be too much to include in the record, I should like to suggest that you include at least the following:

"The very thoughtful remarks of Commissioner Crawford, of the Food and Drug Administration; the discussion on legislative controls by Dr. F. M. Peters, Jr., vice president of the Quaker Oats Co. of Chicago; and the brief summary of the MCA approach to proposed changes in the present law given by G. J. Williams of the Dow Chemical Co."

I suggest, Mr. Chairman, that those three statements be put into our record, as suggested by the Manufacturing Chemists' Association.

The CHAIRMAN. It is so ordered.

(The statements referred to are as follows:)

REMARKS OF C. W. CRAWFORD, COMMISSIONER OF FOOD AND DRUGS, FEDERAL SECURITY AGENCY, ON THE FOOD AND DRUG ADMINISTRATION'S VIEWPOINT ON CHEMICALS IN FOOD

(Interindustry Conference on Chemicals in Foods sponsored by Manufacturing Chemists' Association, Inc.)

I am grateful for the opportunity to present the views of the Food and Drug Administration to this Conference on Chemicals in Foods. I am sure we all agree that the law must protect the public health against danger from the use of toxic or deleterious substances in food. I am also sure that we would find wide

areas of agreement on the many things that legislation on this problem should contain or should not contain, if we fully understood each other's viewpoints. Most of the differences obviously arise from misunderstandings that ought not to exist. For this reason we in the Food and Drug Administration have urged representatives of your association, after the few brief talks we have had with them about the problem, to return for further and more comprehensive discussions. Let me renew that invitation here again.

Much confusion has come from the convenient but inaccurate reference to the problem by the expression "chemicals in food." The ineptness of that expression is apparent when we consider that foods themselves are chemicals, and that the living organism which consumes food is itself a complex of chemicals in which uncounted chemical reactions sustained by food are continuously occurring.

If we are to understand the real problem, its nature and its scope, we must define it more precisely. To use the term "new chemicals in food" does not help much because the real question does not necessarily involve the newness of the chemical. Nor would it help much to define it as "dangerous chemicals in food." That expression covers too much territory. Where the nature and extent of the danger from the use of a chemical in food is known, existing law deals with it effectively.

To appraise the need for new legislation on chemicals in food we should consider just what provisions relating to this question are in the law now. From the text of the Federal Food, Drug, and Cosmetic Act we see that it defines any food as adulterated (1) if it contains a poisonous or deleterious substance which may render it injurious to health; or (2) if it contains any such substance that is not required in the production of the food or that can be avoided by good manufacturing practice; or (3) where it is so required or cannot be so avoided, if it exceeds the tolerance prescribed by the Federal Security Administrator after public hearing.

In prescribing a tolerance the law directs the Administrator to take into account the extent to which the poisonous or deleterious substance is required or cannot be avoided in the production of each food, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. In every event the Administrator is enjoined to prescribe the tolerances at such levels that the public health will be protected.

Reading the statute impresses one with the clear intent of Congress to go further than merely insuring that no single food will itself carry enough poison to jeopardize the health of the consumer. The purpose was to safeguard the Nation's food supply so that the over-all quantity of toxic substances, in all the items that make up the varied diet characteristic of American people, will be held at safe levels.

The language chosen to prevent the unnecessary addition of poisonous or deleterious substances is worthy of careful study. Traffic in food containing such a substance, in any quantity whatever, is prohibited "except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice." While the meaning of the word "required" has not yet been interpreted by appellate courts, it seems fair to assume that a real or fancied improvement or advantage resulting from an added poison would not be enough; that to satisfy the law the added substance actually must be essential to production. It appears that Congress regarded the addition of poisons to our food supply as too hazardous to permit except in the face of real necessity.

Some further light on the intent of Congress is shed by committee reports on the bill which became the present law. The following is a quotation.

"* * * In promulgating such regulations [prescribing tolerances] this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessities of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount of poison in a particular food to very small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add dangerously toxic substances to foods * * *."

The purpose of Congress to exclude from the Nation's food supply poisonous or deleterious substances, in whatever quantity, unless those substances are

actually required in producing that food, should be kept clearly in mind in considering the problem of chemicals in food.

Let us turn now from the general policy and pattern of the law to a study of its specific provisions. A food is defined as adulterated, first, "if it bears or contains any poisonous or deleterious substance which may render it injurious to health," and second, "if it bears or contains any added poisonous or added deleterious substance * * * except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice * * *." An essential element of proof common to both these provisions is that the substance in issue is in fact poisonous or deleterious. Unless that fact is known the law does not operate; surmise that it might be poisonous is not enough.

A third provision defines a food as adulterated "if it bears or contains any added poisonous or added deleterious substance * * * required in the production thereof" in "any quantity exceeding the limits fixed" in regulations prescribing tolerances for the protection of the public health. Of course no limit on the quantity of the substance can be fixed for this purpose without knowledge of just how toxic it is and within what specific limits it is safe.

If this knowledge does not exist and no tolerance can be established we might consider action under the provision we discussed a few moments ago against any food containing a poisonous or deleterious substance which may render the food injurious to health. Here we run into the second element of proof required by this provision—proof that the quantity of the substance present is such as may render that food injurious to health. Unless the substance has been sufficiently tested to give a clear picture of the degree of its toxicity there is bound to be a gap of uncertainty within which the quantity of the substance may fall and where no legal action can be taken, notwithstanding the fact that no one knows whether the food is injurious or not. The zone of uncertainty is widened when the substance is used, as has been done, before quantitative methods for its determination in the food have been worked out.

With this background on existing law let us try to define the question before this conference. Certainly the terms "chemicals in foods," "new chemicals in foods," and "dangerous chemicals in foods" all lack much in precision. It seems to us that the real question is on the use in food of any substance of whatever nature, whether in lay parlance it is a chemical or not, whether it is new or not, when that substance has not been adequately tested, either through human experience or by all reasonably applicable laboratory and clinical procedures, to show either that it is not poisonous or deleterious, or, if it is and it is required in the production of a food, that it can be safely used.

This is the relatively narrow but highly important area in which we believe that neither the Federal Food, Drug, and Cosmetic Act nor any other law affords adequate protection to the public health.

It would be both unfair and incorrect to appraise this problem on the assumption that we have an irresponsible chemical industry and an irresponsible food industry, both callous to the health of consumers. Nor can we appraise it on the assumption that this is just a bureaucratic grab for dictatorial powers over the food and chemical industries. The facts belie both assumptions; but the facts show that there is a fringe of the careless or ignorant or unscrupulous who have used or are now using chemicals in food without sufficient testing to be reasonably certain they will not impair the health of consumers. We have seen insecticides marketed before toxicity tests were made, other than those required to show the LD_{50}, and before adequate quantitative analytical methods were developed. We have seen the paradox of vigorously pressed sales campaigns for chemical additives while tests to discover unknown facts about their toxicity were being planned or carried out.

That the dramatic equivalent of the elixir sulfanilamide disaster of 1937 that cost more than a hundred lives has not occurred in the food field speaks volumes, first, for the conscientiousness of these industries generally, and second, for the providential luck of the fringe operators—and of the public. We have had some narrow escapes.

Much has been said about the impossibility of guaranteeing the absolute safety of any food additive for all people under all circumstances, and about the toxicity of nearly every common food to hypersensitive individuals. The point is well taken; but this does not mean that nothing should be done toward setting up legal safeguards to minimize other and more avoidable dangers. A practical, common-sense solution can be worked out if the nature and scope of the problem are clearly recognized and if a constructive approach is followed.

Leaders in the food and chemical industries have set some practical guidelines. In their investigations of the prospective use in food of chemicals of

unknown safety they have used every reasonably applicable test. Each point on which the chemical might be suspect is thoroughly explored. It is not until every reasonable check has been made, all with negative results, that the chemical is put into use. This procedure is not only highly desirable; it is highly expensive. We believe that what is being voluntarily done by the majority should be required of those who are less conscientious and who may prematurely launch competitive products at the risk of consumer health and to the detriment of returns from properly tested products. An amendment to accomplish this objective need not disturb the present majority practice, or any provision or procedure of existing law.

The objective would not be accomplished by the suggested amendment to provide that the Food and Drug Administration be notified of the intent to add to any food an ingredient that has not previously been used in that food. Mere notification requires no prior testing; and testing takes time, no matter whether it is done by the sponsor of the chemical, the Food and Drug Administration, or anyone else. Such an amendment would be practically valueless in preventing the use of chemicals of unknown toxicity, and in protecting consumers from being used as guinea pigs.

Much criticism has been directed at the amendment proposed in the Miller bill, H. R. 3257. I must accept personally all blame for any imperfections of that bill. I drafted it, rather hurriedly, at the request of the Delaney committee, of which Representative Miller is a member. In presenting it to the committee I emphasized the fact that it was purely tentative and that it could be improved. It was my hope, and I am sure it was the hope of the committee and of Dr. Miller, that the draft would aid in crystallizing constructive opinion on the problem.

I used as a general pattern the new drug section of the law. What classifies a new drug as such is usually the fact that it contains some chemical that is not generally recognized by qualified experts as having been adequately tested for safety. As I saw it, there was no significant difference in the basic problem arising from the use in drugs of chemicals inadequately tested for safety and that from the use in food of chemicals inadequately tested for safety. The differences seemed relatively minor and could be dealt with through changes in draftsmanship.

Let me illustrate how I envisoned the general working of the bill, regardless of the sufficiency of its language. A manufacturer finds that certain kinds or classes of food can be improved by adding a chemical. That chemical is not required in the production of these foods, nor is it generally recognized by qualified experts as having been adequately tested to show that it is not poisonous or deleterious.

The manufacturer tests the chemical by all reasonable applicable methods to supply this information. He focuses his study on the chemical itself rather than on foods containing it in quantities he considers using. If he finds that it is poisonous or deleterious—that it causes harm when ingested in any quantity in which it can readily be consumed—he should abandon the project. Public policy as expressed in existing law forbids the unnecessary use of such substances in food.

If he believes the tests show that the chemical is not poisonous or deleterious, he submits all his data with an application to the Federal Security Administrator for use of the chemical in food. If the Administrator agrees with him the application is made effective. So far as any provision of the law concerning poisonous or deleterious substances is concerned, the applicant can then use the chemical or sell it for use in food of any kind. Other provisions of the law on adulteration and misbranding would of course have to be observed.

If the Administrator believes the data leave a reasonable doubt as to whether the chemical is poisonous or deleterious, the applicant will be so advised. If he wishes, the applicant can do additional work on the point in question or he can demand a formal hearing before the Administrator, at which a record will be made of all evidence on both sides of the question. If the Administrator is still unconvinced he issues an order refusing to permit the application to become effective. The applicant can appeal the order to the Federal courts, which have power to set it aside if it is unreasonable or arbitrary.

Let us take as a second illustration a chemical which is known to be toxic and which the manufacturer wants to sell for use in destroying predatory insects on one or more food crops or groups of food crops. It is well recognized that the use of some poisonous or deleterious substance is required in producing these crops. The manufacturer tests the chemical by all reasonable applicable methods to determine the degree of its toxicity. He develops quantitative an-

alytical methods for the chemical in or on the foods, unless such methods already exist. He determines the quantities of the chemical remaining in or on the foods, as they are shipped in interstate commerce, when the chemical has been used on the crops at such times and in such quantities as will accomplish its insecticidal purposes.

If he believes the investigation shows that such foods are safe for consumption, he submits his application to the Administrator, accompanied by reports of all his results. He will recite the directions he proposes to use in labeling or otherwise in marketing the article for use on specified food crops or groups of food crops, spraying or dusting schedules, and if necessary precautions such as the latest date for safe application before harvest.

If the Administrator agrees with him, his way is cleared to sell the chemical for use under the directions he proposed. Those who buy it and use it in accordance with these directions will be free to market those crops in interstate commerce. If someone uses it in greater quantities, that is the responsibility of whoever does so. Existing provisions of the law still apply, an authority to provide tolerances can be exercised. If someone wishes to use it for food crops other than those included in the directions, it is the responsibility of that person to submit an application covering such use.

If the Administrator believes that the data submitted by the manufacturer leave a reasonable doubt that the foods will be safe, the procedure for notification, hearing, and court review is the same as that described in the illustration on a chemical that is not required in producing food.

In drafting the Miller bill an effort was made to fix responsibility for compliance upon the firm or person who sponsors the use of a chemical in food or in circumstances where it is likely to contaminate the food. If the language is not clear in this respect it should be changed to make it so.

I did not include a so-called grandfather clause in the bill parallel to that in the new drug definition because I did not regard the problem as parallel. This clause excluded from the definition those drugs that had been on the market before the law was passed. In 1938 Congress was enacting two entirely new provisions to guard against dangerous drugs. The first covered any drug that is dangerous to health when used in accordance with directions on its label. The second was the new drug provision, early drafts of which defined a new drug simply as one not generally recognized by qualified experts as safe for use under the conditions set forth in its labeling. It thus included drugs then on the market that were generally recognized as dangerous and that would therefore be subject also to the first provision. Congress decided to limit the new drug section to drugs that were truly new, and to subject drugs previously on the market to the other provision. To prevent overlapping of the two provisions, Congress modified the definition of a new drug by writing the grandfather clause into it.

In the situation now before us the law contains adequate provisions on chemicals of known toxicity in foods. We have only one gap to close, rather than the two that were to be closed in the drug law. The gap we now have to close is that through which chemicals of unknown toxicity and potentiality for harm find their way into our foods. To prevent the overlapping of provisions now in the law covering substances of known toxicity, the scope of the proposed amendment was limited to those substances not generally recognized by qualified experts as having been adequately tested. If the public is to be protected from the hazards of inadequately tested substances in food, the time of the beginning of use of such substances, whether before or after enactment of the proposed amendment, is immaterial.

It is not intended to require further testing of any substance that is generally recognized by qualified experts as having been adequately tested. I cannot share the concern expressed that the proposed bill would stop for an indefinite time the use of chlorine in food sanitation or potassium iodide in iodized salt or vitamins and minerals in food enrichment. These are recognized by experts generally as having been adequately tested for safety, and therefore would not be subject to the proposed amendment.

If doubt exists as to whether experts generally recognize that a chemical now being used has been adequately tested to show its safety, a provision for the amendment to become effective at a specified date after enactment could afford ample time for clearance if the chemical has in fact been adequately tested and is safe. This would safeguard the public, and also the equities of manufacturers who themselves had paid the price of adequate testing. To exempt from the amendment those who had not done so would leave no compul-

sion for them to shoulder the expense; by doing nothing they could shift the burden to the Government.

In approaching the task of draftsmanship the Delaney committee asked me to do, there were several factors that persuaded me to follow the general pattern set up by the law for new drugs. These provisions have worked smoothly and satisfactorily since 1938, during which time applications have become effective for nearly 6,000 new drugs. Among these are the many so-called wonder drugs which constitute the most spectacular progress in drug therapy of all time.

In one minor case only has litigation arisen over the Administrator's refusal to permit a new drug application to become effective. This practical absence of litigation has resulted from the fact that, while we have no formally established advisory committee, in every case where a serious question arose we have consulted the outstanding research workers and clinicians in the particular field involved, whoever and wherever they might be.

The problems from the use of drugs inadequately tested for safety and the use in foods of chemicals inadequately tested for safety are fundamentally alike. It seems to me that the time-tested pattern for new drugs should be followed rather than to undertake some new and untried legislative pattern, the effects of which cannot be so clearly foretold.

The new drug section has been highly effective in protecting the public health. Although the drug industry expressed grave apprehensions about the enactment of that section, they have since become its enthusiastic supporters. Confirmation of this came shortly before the Miller bill was introduced in The Odyssey of Modern Drug Research, by Robert Burlingham, a book published by The Upjohn Co., one of the country's leading drug manufacturers. Let me read some quotations relating to the new drug section:

"At the time [of enactment] many of the drug manufacturers affected considered the law practically as bad as the medicine that brought it on. (The leading pharmaceutical houses did not take quite so lugubrious a view, since they had argued against the bill on the ground that they already had higher standards of quality and safety control than the law would provide.) Nevertheless, the entire industry settled down to observing the law and the complex regulations issued under the wide enforcement powers granted to the Food and Drug Administration. And in the course of doing so, the manufacturers—some willy, some nilly—found themselves compelled to increase their scientific and technical personnel, to accumulate a vast body of medical evidence on which to launch their products, and in general to apply the principles of rational therapeutics to all their works. * * *

"It is to the credit both ofthe FDA officials and of the drug manufacturers, who have worked in full cooperation to meet the objectives of the law, that the public has been given needed protection from careless or irresponsible drug making, without any hampering of the free enterprise of drug discovery. On the contrary, as already pointed out, the law gave new impetus to pharmaceutical research and new strength to the ties between drug houses and other medical research facilities outside the industry. Although industry and FDA points of view have often differed and sometimes clashed on administrative matters—which, in this case, are almost entirely matters of opinion—a large majority of the industry would certainly be among the first to recommend a head examination for any manufacturer who wanted to repeal the new drug provisions of the law at this late date. * * *

"It is true that most of the big-name, full-line houses—houses like Lilly, Upjohn, Squibb, Abbott, and Parke, Davis, for example—had long maintained rigorous manufacturing controls, high quality standards, large-scale pharmacological and clinical testing of new products, and other standards which the new law compelled the whole industry to adopt. But there is no indication that the law has wrought hardship on any company, large or small, except perhaps for its desirable discouragement of fly-by-nighters who might otherwise have exploited and possibly endangered the public. On the contrary, the law has profited the whole industry to the extent that the public, including the medical profession, now takes for granted the purity and quality of all drugs on the market and their safety when used in accordance with labeled instructions. * * *"

Notwithstanding the reasons I had for adopting the pattern of the new drug section, I do not wish to discourage consideration of other approaches. Every reasonable proposal should be explored. If someone can come up with a better solution I shall share the gratification everyone concerned will feel.

Of course the Congress will make the final decision. Congress will decide whether an amendment is needed and if so what the amendment shall be. Con-

gressional policy will determine whether the initial decision on the safety of a chemical should be made by the administrative agency, subject to court review for its reasonableness, or as has been proposed, by Federal courts and juries.

Legislators will have to weigh the advantages and disadvantages of each of these two ways. They will have to compare the competence of law courts and juries to resolve these scientific questions from expert testimony presented under the rules of evidence, with that of an administrative body having the advice of its own scientific staff and of experts throughout the country. They must consider the degree of nonuniformity to be expected in decisions on similar questions by different courts and juries throughout the country, and the expected uniformity in such decisions from a single continuing tribunal. They must calculate the risk that bureaucratic concepts may influence administrative decisions and weigh that in the balance.

The manufacturing chemists of this country have been a powerful and constructive influence in the progress of our Nation and in building its strength. The straight, decisive and courageous thinking that has characterized the industry, its ability to recognize facts in complex confusions with fancy and surmise and theory, can be applied with advantage to the problem before us today. In its solution you can be of great help to the Congress and to the people it represents.

I am wholly confident that the conclusions you reach from your meeting today and the resulting actions you take will be a constructive service for the Nation's welfare.

REMARKS OF DR. F. N. PETERS, JR., VICE PRESIDENT, CHEMICAL RESEARCH, THE QUAKER OATS CO., CHICAGO, ILL., ON LEGISLATIVE CONTROLS ON RESEARCH AND DEVELOPMENT IN FOODS

(Inter-Industry Conference on Chemicals in Foods, sponsored by Manufacturing Chemists' Association, Inc.)

There is not sufficient time today to discuss all the effects legislation can have on research, nor even to examine how these would vary with different types of laws. Therefore, this paper will deal primarily with what can happen to food research under a specific kind of legislation which has been proposed.

Presumably, everyone agrees that the public is entitled to the best and purest foods that can be produced; that progress toward better foods can most easily be made along the avenue of research; that the addition of chemicals to foods is not harmful per se and, finally, that most food and chemical manufacturers as well as most members of the Food and Drug Administration are reasonable, honest, and sincerely devoted to serving the public faithfully. When disagreements arise, it is the road to be traveled and not the goal to be reached that is the subject of argument.

It surely will be accepted that the industrial application of research is synonymous with change. To a large extent, industrial research laboratories are seeking changes which will (*a*) result in improved or entirely new products, (*b*) gain some competitive advantage, (*c*) produce lower cost operations, or (*d*) give a financial return from licensing or sale of patents. If management's freedom to make changes in its products is destroyed, then its incentive to support research is eliminated.

The output of a research laboratory is the fruit of the combined creative power of its individual staff members. The greatest thrill a research worker experiences is the application of his brain child to a useful purpose. Nothing destroys his morale faster than failure of management to adopt constructive suggestions presented by the research group. Whenever the individual research man reaches the conclusion that management cannot or will not adopt new ideas, his attitude toward his work and his employer will change for the worse.

Legislation has been proposed which would destroy the freedom of management to use its best judgment in adopting research findings. In March, 1951, Representative Miller introduced a bill, H. R. 3257, the principal provisions of which are as follows:

A manufacturer must file an application and obtain permission from the Federal Security Administrator before using any substance designed to alter food in any way if that substance "is not generally recognized * * * as having been adequately tested to show that it is not poisonous or deleterious." The application must be accompanied by a great deal of technical information. It may be denied for several specific reasons but attention is called to the final

basis for rejection. The Administrator may issue a denial if "on the basis of any information before him with respect to such chemical, he has insufficient information to determine whether such additive is safe for use."

An appeal from the ruling of the Administrator may be made to a circuit court whereupon the Administrator will file a transcript of the record upon which refusal was based. The bill then states, "The finding of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive."

This legislation, if it becomes law, will destroy a manufacturer's freedom to make changes in his products. In the first place, any change in any food, whether made by addition of a new ingredient or whether produced by a new method of processing would be submitted by the prudent manufacturer to the Federal Security Administrator for approval. It will be said that the intent of H. R. 3257 is to require prior-use approval only if new or untried additives are involved. That may be the intent today but the prudent man will read the law and reason differently. If his proposed food has a new appearance, flavor, texture or odor, whether because of new ingredients or new processing methods, such food contains chemical additives as defined in this bill. If it is new it certainly is not "generally recognized" as either safe or unsafe. It has not been recognized, period. Therefore, the prudent manufacturer will submit every new food product for approval before marketing.

Thus, the real authority to adopt research discoveries is removed from the manufacturer and transferred to the Federal Security Administrator, an appointee of the President. No clairvoyance is needed to know what such a transfer of authority will do to research. Even if financial support were not withdrawn, the effect of the morale of research men would be no less calamitous. All their ideas, all their efforts would be directed toward what would please the Administrator rather than toward what would be better in their own judgment. The judgment of a single man would be substituted for the free judgments of thousands and tens of thousands of research men throughout the country.

Of course, it might be that the Administrator would scrutinize carefully only applications involving chemicals never used before and would automatically approve everything else. However, what might happen and what can happen may be quite different. A rudimentary knowledge of human behavior will show that the Administator cannot accept changes easily. Under this bill, the ultimate responsibility for the absolute safety of every new food is placed squarely on the Federal Security Administrator. This responsibility is too great for any individual. Acceptance of a new product means nothing to the Administrator financially, he gains no competitive advantage, he cannot claim the doubtful glory of being the inventor. All he can gain is more responsibility—responsibility for what will happen when any approved food is eaten by any one of 150,000,000 persons. Under such circumstances he will do what any man would do under similar conditions. He will approach the question of decision with a negative attitude. His degree of negativity will increase in proportion to the breadth of the new discovery. Progress through research and a negative attitude toward change are not compatible.

This suggests a corollary point. If any improvement is revolutionary, it is probably patentable. If it is covered by patents little pressure will be put on the Administrator to approve the use of the invention except by its owners. The normal reluctance of the Administrator to assume added responsibilities will be supported by the negative or at best, the indifferent attitude of those in industry not in position to capitalize on the invention. It is not inconceivable that the price of acceptance might be surrender of patent control. If protection under patents resulting from research is weakened or jeopardized, another incentive for support of research is destroyed.

Suppose a manufacturer develops a change that lowers his costs, but in his opinion, does not affect nutritive qualities. Will the Administrator quickly approve a change if the only benefit is to the manufacturer?

Since it must be admitted the Administrator could prevent change, is it not the manufacturer protected from the danger of arbitrary rejection or from a completely negative attitude on the part of the Administrator by his right to appeal to the courts for relief? Unfortunately, the answer is "No." Under H. R. 3257, there is no practical means of obtaining relief from the judgment of the Administrator, even though a court might be convinced that he acted unwisely or capriciously. The decision of the court must be based on findings of fact presented by the Administrator. The exact wording of the bill is "The finding of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive." A circuit court judge once said, "Give me the right to fix the facts

and you may have the right to declare the law."[1] The Supreme Court said, "The findings of the Administrator as to the facts, if based on substantial evidence, are conclusive."[2] Substantial evidence does not mean a preponderance—it does not even mean evidence presented by the most eminent or best qualified witnesses. In practical experience it means a scintilla or bare thread. Anyone familiar with administrative hearings during the past dozen years can recall cases where the testimony of a single witness, an employee of the Administrator was considered as "substantial evidence." Instances are known where "findings of fact" ignored testimony of several qualified industry witnesses and were based instead upon the testimony of a single Government employee.

Thus, under H. R. 3257, the Federal Security Administrator has complete control of what research developments can be commercialized and the manufacturer has no practical relief by appeal. This absolute power to control the application of research carries with it the power to destroy industrial research.

But suppose the Administrator does not develop a negative attitude but possesses the superhuman qualities that would allow him to assume ever increasing responsibilities without the spur of incentives. He still must be assured of the safety of new chemicals in foods, the safety on new processes. Each application must be carefully reviewed. Under any conceivable conditions, this means time—it means delay in the application of research. It may mean loss of a competitive advantage for the manufacturer. The more conscientious, the more devoted the Administrator is to the public interest, the more time he will take to study applications. Give the power to control the rate of change and you have given the power to control the rate of research.

Some may feel that this paper has made the worst possible interpretation of the results stemming from the proposed legislation. There are three answers to this. First, nothing has been predicted which could not happen if H. R. 3257 becomes a law. Second, the alleged need for H. R. 3257 is based on the worst possible interpretation of the acts of the food industry. It is based, not on what has happened in the past but on what could conceivably happen in the future. Third, what may happen to food research under this bill should be considered in the light of what has happened under previously enacted legislation.

Before adoption of the Food, Drug, and Cosmetic Act of 1938, Senator Copeland, sometimes called the father of this act, said in reference to the standard-making provision of one of the predecessor bills, "It should be noted that the operation of this provision will in no way interfere with the marketing of any food which is wholesome, but which does not meet the definition and standard * * *"[3] Mr. Walter G. Campbell, then Chief of the Food and Drug Administration in testimony before a House committee said, "There can be no objection to the philosophy that any article that is wholesome and has food value and is sold for what it is, without deception, should be permitted the channels of commerce."[4] In spite of these positive assertions, within a few years the sale of farina enriched with vitamin D had been outlawed under the very provision of the act that Senator Copeland said would not produce such a result. There was nothing wrong with the product or its label—It merely did not conform to an arbitrary definition set by the Administrator subsequent to the passage of the act.

The introduction of enriched corn meal was delayed for at least 2 years because of uncertainty as to whether there would be Federal standards and if so, what they would be. A prominent research director told the speaker he would not willingly spend research money on any food for which standards of identity had been promulgated. Another company opposed the suggestion of setting standards of identity for all breakfast foods, for fear that further developments in this field would be prevented. Another large food company delayed an important research project because even if successful, the product in question could not be sold under present definitions. These are specific examples of research curtailed or threatened—not directly from that which was written into an act in 1938 but because of what the act came to mean after 1938. Similar administrative interpretations and rules in the future can extend the scope of a law passed today.

This paper neither affirms nor denies the need for further legislation. It does assert that legislation giving the Federal Security Administrator power of life or death over new food products will result in loss of industry incentives to

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[1] Judge Curtis L. Waller, Miss. Law J. 17, 212–220 (1946).
[2] *Federal Security Administration* v. *The Quaker Oats Company* (318 U. S. 218 (1943)).
[3] Report No. 361 on S. 5, 74th Cong., Dunn, Federal Food, Drug and Cosmetic Act, p. 246.
[4] Dunn, ibid., p. 1239.

support research, will decrease the amount of research, will lower the morale of research personnel and will progressively reduce the rate of progress in the food industry in the years to come.

REMARKS OF G. J. WILLIAMS, THE DOW CHEMICAL CO., LEGAL PANEL ON "PRESENT LAW AND PROPOSED CHANGES"

(Interindustry Conference on Chemicals in Foods)

You have heard Mr. Smith and Mr. Bartenstein summarize the existing Federal Food, Drug, and Cosmetic Act and the new Miller bill. I have been given the opportunity to present the Manufacturing Chemists Association's approach to changes in the present law.

First, we believe that the present laws relating to pesticides are effective and adequate to protect the American public, and we would not propose any change in the laws relating to these products. My further remarks will not apply to any substance, chemical additive or what you will subject to the Federal Insecticide, Fungicide, or Rodenticide Act.

Second, we believe that the present legislation vests the Government with adequate authority over the use of chemicals in foods. As Mr. Smith has pointed out, it is unlawful to ship in interstate commerce any food bearing or containing an added poisonous or deleterious substance. If this law is enforced, there can be no danger to the public health through the use of chemical additives.

Third, the one area in which the present legislation may need strengthening is in assuring that the Food and Drug Administration is given advance notice of proposed new uses of chemical additives. Today, and we must admit this possibility, a chemical additive can be put to a new use and such use can continue for some time without the Food and Drug Administration knowing anything about it. Enforcement is difficult when you are working under such a handicap as lack of knowledge of violations.

With these facts in mind, the Manufacturing Chemists Association recommends that consideration be given to incorporating in the present law a provision prohibiting any new use of any chemical additive in or on any food until 60 days after notice of such intended use has been filed with the Food and Drug Administration. This notice could be filed by either the manufacturer of the chemical additive or a food processor and should include these things:

(*a*) Applicable pharmacological and toxicological data available.

(*b*) The known composition of the chemical additive.

(*c*) An analytical method for determining residues.

(*d*) Directions for use of the chemical additive with respect to the specific food or foods and the specific use or uses proposed.

(*e*) A sample of the chemical additive.

In addition we would propose that provision be made for conferences between the Food and Drug Administration and the person filing the notice so that the intended use could be further discussed.

We would not propose that the Food and Drug Administration be given the power to deny or the responsibility of approving such use by an administrative decision. We do not favor prior approval or precertification.

If the Food and Drug Administration, after reviewing the submitted data feels that the intended use should be denied because it presents a hazard to the public health, it may proceed under the existing enforcement powers of seizure, injunction, or criminal proceedings as outlined by Mr. Smith.

Printed copies of our approach are available, and we invite your study, comments, and criticism.

How would this legislation work as a practical matter? Suppose a food processor wants to use a chemical additive in canned beets, asparagus, and peas. Either the food processor or the manufacture of the chemical additive would file a notice of the proposed use with the Food and Drug Administration giving the data and other information required. Very probably, the manufacturer of the chemical would furnish the toxicological data, the known composition of the chemical additive and an analytical method. The food processor might furnish the directions for use. Thus, the notice would be a combined effort. Sixty days after filing such notice any food processor would be free to go ahead with the proposed use without any further action by the Food and Drug Administration. Any other use of the chemical additive or any deviation from the use as proposed would be a violation of the law unless a supplementary notice was filed.

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We are convinced that this program of legislation is sound. It protects the public in that no food can be shipped in interstate commerce if it bears or contains any added poisonous or deleterious substances. It is sufficiently flexible to allow for new discoveries and developments. It assists the Food and Drug Administration in that it will have an opportunity of reviewing in advance each and every proposed new use of a chemical additive. Yet it avoids the many disadvantages of administrative finality and leaves to the courts the decision as to whether or not the law has been violated. This is the truly American way of doing things.

Mr. KLEINFELD. The last thing I have is a letter dated February 7, 1952, received from General Mills, Inc. General Mills, Inc., is one of the largest food processors and distributors in the country. In view of the stature of General Mills, Inc., I suggest that this short letter I have be read into the record at this time, and I would like to read it.

The CHAIRMAN. Go right ahead.

Mr. KLEINFELD. This letter is signed by G. Cullen Thomas, vice president of General Mills, Inc., and dated February 7, 1952 [reading]:

As the vice president of our company who has complete administrative responsibility for the quality standards of General Mills food products, I had the pleasure on April 17, 1948, to appear before a subcommittee of the Senate Committee on Interstate and Foreign Commerce in support of the Food and Drug Administration's proposal under the Miller bill, H. R. 4071, to expand its enforcement procedures and jurisdiction in the case of foods which had become adulterated.

We took the view then, and we restate it now, that the courts have very properly charged the food industry with a responsibility and a trust beyond that assumed by the ordinary manufacturer. We of General Mills accept that high degree of public health responsibility as a fit price to pay for the privilege of supplying food products to the general public. Accepting that premise, it is then perfectly understandable, if a bit unusual, for an industry to join with its "policemen" in a voluntary request that it be subjected to additional regulation and control.

We are completely in accord with the principle of the Food and Drug Administration's recommendation that new chemical additives to foodstuffs be approved before use in consumer food products. We believe that a properly framed amendment to the Federal Food, Drug, and Cosmetic Act would serve only to reduce to the form of law, a practice which most of us would follow in good conscience in the absence of such amendment. To reason otherwise would be illogical for, translated, it would suggest that we care only for our business of today and care little for future acceptance and continuing consumer good will.

We disagree with the contention that a proper restrictive amendment would serve to discourage progress in research for we have confidence that the acceptable and desirable new products of research readily will be approved; conversely, we contend that if the new products of research are disapproved as improper additives to foods, it is not that progress has been stopped but that new knowledge has been acquired and dangers have been averted.

We reject also the argument that a properly framed amendment to the act which adopts the general principle of preclearance of new chemical additives to foods would invest the Food and Drug Administration with a tremendously capricious and arbitrary control over the composition of our foods. We have seen no evidence that the comparable new-drug provisions of the act have been administered with anything but a view to the public interest and we have confidence in an agency which has been unswerving in its devotion to that public interest, yet at all times reasonable, cooperative, and realistic in the exactions which it has imposed on producers and manufacturers. The public will ever owe a debt of gratitude for the quality of the administration which has been provided by such officials as Mr. Crawford and his predecessor, Dr. Dunbar.

The CHAIRMAN. Call the first witness.

Mr. KLEINFELD. Our only witness today is Dr. Bruce D. Forsyth. Will you come forward, please?

The CHAIRMAN. Your name and address, Dr. Forsyth?

Dr. FORSYTH. Bruce D. Forsyth, Assistant Surgeon General, United States Public Health Service, Washington 25, D. C.

(The oath was administered by the chairman.)

TESTIMONY OF BRUCE D. FORSYTH, D. D. S., ASSISTANT SURGEON GENERAL, CHIEF DENTAL OFFICER, PUBLIC HEALTH SERVICE, FEDERAL SECURITY AGENCY

Mr. KLEINFELD. Dr. Forsyth, what degrees do you hold?

Dr. FORSYTH. One degree, doctor of dental surgery.

Mr. KLEINFELD. You are not a medical doctor?

Dr. FORSYTH. No, sir.

Mr. KLEINFELD. How long have you been associated with the Public Health Service?

Dr. FORSYTH. I first started with Public Health Service as dental interne December 16, 1931.

Mr. KLEINFELD. Have you been with the Public Health Service since that time?

Dr. FORSYTH. Ever since.

Mr. KLEINFELD. And how long have you been Assistant Surgeon General and chief dental officer of the Public Health Service?

Dr. FORSYTH. Since May the 17th, 1948.

Mr. KLEINFELD. Have you written any publications, any papers, on the question of fluoridation of drinking water?

Dr. FORSYTH. Not I, personally; but more than 100 papers have been published by our research workers. I have published several articles but not on the fluoridation of community water supplies.

Mr. KLEINFELD. Not on fluoridation?

Dr. FORSYTH. No.

Mr. KLEINFELD. Does your statement represent the official viewpoint of the Public Health Service?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. Will you please read your statement.

Dr. FORSYTH. Mr. Chairman and members of the committee:

I am glad to meet with the members of this committee at the request of your chairman to read a prepared statement expressing the views of the United States Public Health Service on the fluoridation of drinking water.

The water fluoridation policy of the Public Health Service was clearly stated by Surgeon General Leonard A. Scheele in his testimony before the Senate Subcommittee on Appropriations, on April 24, 1951. At that time he said:

> During the past year our studies progressed to the point where we could announce an unqualified endorsement of the fluoridation of public water supplies as a mass procedure for reducing tooth decay by two-thirds.

This policy statement is supported by a tremendous amount of research conducted during the first half of this century, particularly during the past 25 years, on the chemical characteristics of fluorides and their physiological effects on humans. The statement is based on extensive epidemiological studies conducted in many communities having 1 or more parts per million of natural fluorine in the drinking-water supply.

Now that means 1 part of fluorine per 1 million parts of water. In this country there are more than 3 million persons who have lived all their lives in such communities. It is based on the results of studies concerned with the fluoride content of food and the absorption of fluorides by the human body. It is based on extensive studies designed to determine the dental and other physiological effects resulting from the use of fluorides in food and water. And finally, it is based on a series of pilot programs; programs designed to test on a community-wide basis the dental and other physiological effects of adding fluorides in controlled amounts to the drinking-water supply. The pilot studies have also provided first-hand experience in the purely technical phases of water fluoridation. Three such pilot programs were begun in 1945, two in this country, one in Grand Rapids, Mich., and one in Newburgh, N. Y., and a third in Brantford, Ontario. Similar projects were started in 1946 or later in Sheboygan, Wis.; Marshall, Tex.; Evanston, Ill.; and Lewiston, Idaho. In view of the wealth of evidence obtained from all of these fluoridation studies—both in the laboratory and in the field—it can truly be said that never before has a public-health measure been subjected to such thorough scientific scrutiny before being recommended as a standard procedure.

Before a procedure is recommended for public-health application, one of the first questions which must be answered with an unqualified "Yes," is "Is the measure safe?"

At this point a brief historical résumé might be in order. A careful analysis of the extensive data which I have mentioned shows that excessive amounts of fluoride in the drinking water can cause mottled enamel. In fact, most of the early studies on the relationship of fluorides to dental health were concerned with mottled enamel, or dental fluorosis, which was shown in 1931 to be caused by excessive amounts of fluorides in the drinking-water supply. Careful epidemiological investigations demonstrated that as the fluoride concentration increases above 1 part per million, there is an increase in both the percentage of individuals afflicted and in the severity of the mottling. But these studies also showed that a concentration below 1.5 parts of fluorine per million parts of water produced no mottling of esthetic consequence. This finding led to the establishment in 1942 of 1 part per million and in 1946 of 1.5 parts per million as the maximum fluorine concentration acceptable under the requirements of the Publec Health Service drinking-water standards. So, the level of 1.5 parts per million was actually set as a safe level for water standards several years before the recommendation was made that fluorides be added in optimum amounts to prevent tooth decay.

The results of the laboratory and epidemiological studies on humans and animals also have demonstrated that mottling of the teeth is the first sign of undesirable effects of excessive fluorides. Mottling of the teeth occurs at far lower concentrations than do any other undesirable effects. Fluorine balance studies have demonstrated that fluorine in water, up to 5 parts per million, is efficiently excreted by the human body. Furthermore, studies of individuals using drinking water containing up to 5 parts of natural fluoride per million parts of water showed that there are no undesirable effects on bone structure. There are no signs of increased fragility, no signs that the bones are harmfully affected in any way. It has been thoroughly established that

teeth are the first parts of the body to be affected by the lower range of fluorides concentrations.

No evidence has ever been produced that 1.0 part per million of fluoride in drinking water has or will harm any living person or thing. Incidentally, 1 part per million is the general term for the amount recommended for the major portion of this country. Actually the concentration is adjusted upward to 1.3 or even 1.5 for the Northern States and slightly downward for the Southern States to as low as 0.6 for the hot, dry, desert-like climate of certain parts of Arizona. This adjustment is made in relation to climatic and seasonal factors which influence per capita water consumption.

I have already answered the next practical question, "How much good will it do?" Field studies conducted in this country and in other parts of the world conclusively demonstrated that where drinking water contains roughly 1 part per million of natural fluoride, tooth decay rates are two-thirds lower than in nonfluoride areas. The results of laboratory animal studies showed that an appreciable reduction in tooth decay is brought about by adding the fluoride to their drinking water. Even more important, the pilot programs which I have described demonstrated that children who drink fluoridated water from birth have two-thirds less tooth decay than children the same age living in the same communities had before fluoridation. Furthermore, children who begin to drink fluoridated water several years after birth also receive substantial benefits.

Many persons have concluded from this that the benefits of fluoridated water are limited to children. This is not true. Studies of adults using natural fluoride-bearing water throughout life show they have about two-thirds less tooth decay than have adults drinking fluoride-free water. They have lost only about one-fourth as many teeth. The same thing, of course, will occur in communities which are now adding fluorides to their water supplies.

A third factor to be considered in recommending any public health measure is the expense involved. A conservative estimate of the money value of fluoridated drinking water indicates that for every dollar spent for water fluoridation, $60 to $70 will be saved in terms of needed dental care. It is clear then that no community can afford to postpone water fluoridation. To do so is extremely costly, not only in terms of dental health but also in terms of dollars and cents.

Of course, there are other factors to be considered besides safety and the benefits which will accrue from the application of a public-health measure. One of major importance is the question of technical difficulties involved in applying the procedure. In this respect, water fluoridation is almost an ideal public-health procedure. It can be done simply by trained waterworks operators, who are familiar with the precautionary measures needed in handling fluoride compounds, who can make the tests for fluoride concentration, and who are acquainted with the operation of feeding equipment. The feeding equipment is the same as that long used by waterworks operators in feeding other chemicals into water supplies. Mechanical difficulties, should they occur, lead to underfeeding rather than to overfeeding. Fluoride concentration is determined by chemical tests and then double checked by a comparison of the weight of fluorides fed into the water supply with the volume of water treated.

The fluoride concentration of the water supplies in Grand Rapids, Mich.; Newburgh, N. Y.; and Brantford, Ontario, has been maintained at 1.0 part of fluorine per million for almost 7 years with remarkable ease. However, I do not wish to imply that untrained, uninformed operators are to be given the responsibility for maintaining a fluoride concentration of 1.0 part per million. I do wish to state emphatically that the feeding of fluorides presents no problem to the average waterworks operator who has received specific training in this field. While on this subject I would like to point out that the margin of safety between optimum amounts and toxic amounts is so wide as to cause no concern. To say that a saboteur by one turn of a valve could poison the people of an entire community is utterly ridiculous. At a concentration of 1.0 part per million an individual would have to drink 400 gallons of fluoridated water at one sitting to receive a poisonous dose of the chemical. More than a 2-year supply would have to be dumped into the water supply in 1 day to deliver a seriously toxic dose.

It is, of course, impossible within the limitations of this statement to bring you more than a summary of the voluminous research background of water fluoridation. It is this solid foundation of research which has formed the basis for the water fluoridation policy of the Public Health Service. Also of vital importance is the fact that a similar policy has been adopted by such other national organizations as the American Dental Association, the American Public Health Association, the Association of State and Territorial Health Officers, the Association of State and Territorial Dental Directors, the American Association of Public Health Dentists, the National Research Council, and more recently the American Medical Association.

In my opinion, not one of these organizations would endorse water fluoridation if they had a single reservation regarding its safety, its practicability, or its value in terms of dental health.

Again, in my opinion, it is one of the most remarkable public health preventive developed in this country. It is not a question—can the community afford to fluoridate its drinking-water supply, but can a community afford not to fluoridate?

Mr. Chairman, I want to thank you for the opportunity to appear before you, and I will be very happy to answer any questions that you may have.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Forsyth, I have here a booklet entitled "Better Health for 5 to 14 Cents a Year Through Fluoridated Water," prepared by the Division of Dental Public Health, Federal Security Agency, Public Health Service. Are you familiar with that?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. On page 22 there is a section entitled "Endorsements of the Fluoridation of Public Water Supplies."

Although your statement did advert to these endorsements, I think the record should indicate the nature of some of these endorsements.

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. For example, the American Dental Association, at a meeting October 30-November 2, 1950, stated in part:

> Whereas these data provide convincing evidence of the safety of this procedure and of its benefits in terms of reduced incidence of dental caries: Therefore be it

Resolved, That in the interest of public health, the American Dental Association recommends the fluoridation of municipal water supplies when the fluoridation procedure is approved by the local dental society and utilized in accordance with the standards established by the responsible health authority.

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. That is in general accord with your policies?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. And similarly, on June 8, 1950, the Association of State and Territorial Dental Health Directors resolved—

That the State and Territorial Dental Health Directors recommend the fluoridation of public water supplies for the partial control of dental caries, where the local dental and medical professions have approved this program and where the community can meet and maintain the standards required by the State health authority.

That too is what you refer to?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. And similarly the American Public Health Association, at is annual meeting in November 1950, said:

Whereas accumulated evidence indicates a sound basis for the fluoridation of public water supplies for the partial control of dental caries: Therefore be it *Resolved*, That this procedure be recommended as a safe and effective method for reducing the prevalence of dental caries.

There is one endorsement here which is a little puzzling, sir. On page 23 of that booklet, under "Endorsements of the fluoridation of public water supplies," there is a statement made by the American Water Works Association on June 1, 1949, which says, and I quote:

In communities where a strong public demand has developed and the procedure has the full approval of the local medical and dental societies, the local and State health authorities, and others responsible for the communal health, the water departments or companies may properly participate in a program of fluoridation of the public water supplies.

Is that really an endorsement, sir?

Dr. FORSYTH. Actually, I believe the American Water Works Association feels that they should not endorse something that is a matter for medical or dental concern; that they are concerned with how the thing would operate. It is really not putting the stamp of recommendation as such on it, since they are not really in the medical and dental research field.

Mr. KLEINFELD. In other words, they are not in a position to endorse it, are they?

Dr. FORSYTH. That is right.

Mr. KLEINFELD. I think that is borne out by a letter in a recent issue of the Journal of the American Medical Association, November 10, 1951, volume 147, No. 11, where the Secretary of the American Water Works Association said:

The policy established by the board of directors has not been clearly understood by some, and this letter is intended to clarify the matter. The American Water Works Association is an organization of engineers, administrators, and staff personnel engaged in or interested in the furnishing of public water supplies. It is not an organization of professional men in the fields of dentistry and medicine. It does not promote fluoridation.

In other words, they do not endorse it, do they? They say that if the dental and medical professions say it is all right, they are in a position to go ahead and do it.

Dr. FORSYTH. They don't feel that they are in a position to endorse it.

Mr. KLEINFELD. That is right.

Dr. FORSYTH. As the American Medical Association and the American Dental Association are.

Mr. KLEINFELD. And both of those associations have done so?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. In that connection, I think I might refer to an excerpt from volume 147, No. 14, of the Journal of the American Medical Association, dated December 1, 1951, where the council on pharmacy and chemistry and the council on foods and nutrition of the American Medical Association have authorized publication of a statement entitled "Fluoridation of Water Supplies." In part, the statement says, and I quote:

> After considering the evidence available at this time, the councils believe that the use of drinking water containing up to one part per million of fluoride is safe.

I think that is what you referred to.

Dr. FORSYTH. That is right.

Mr. KLEINFELD. I suggest, Mr. Chairman, this short statement issued by the American Medical Association be made a part of the record.

The CHAIRMAN. Without objection it is so ordered.

(The statement referred to and identified above is as follows:)

FLUORIDATION OF WATER SUPPLIES

The council on pharmacy and chemistry and the council on foods and nutrition have been requested to state their opinion regarding the safety of fluoridation of water supplies, a procedure which has now been adopted by more than 140 cities.

The councils are unaware of any evidence that fluoridation of community water supplies up to a concentration of one part per million would lead to structural changes in the bones or to an increase in the incidence of fractures. The only difficulty so far revealed is a possible increase in mottling of the tooth enamel. The available evidence based on thousands of observations indicates that the incidence of mottling of the enamel in children who drink water containing fluoride up to a concentration of one part in a million is minimal and detectable only by careful dental examination. It occurs only in a small percentage of children and is so slight as not to present a problem from the point of view of appearance or strength of the teeth. Evidence of toxicity other than the effect on enamel has not been reported in communities where the water supply has several times this concentration. After considering the evidence available at this time, the Councils believe that the use of drinking water containing up to one part per million of fluoride is safe. However, the use of products which are naturally high in fluoride content, such as bonemeal tablets, or of lozenges, dentifrices, or chewing gum, to which fluoride has been added, should be avoided where the drinking water has been fluoridated. In places where children are subjected to warm temperatures and consequently drink large amounts of water, a lower concentration of fluoride may be necessary to avoid mottling of the teeth.

Mr. KLEINFELD. Dr. Forsyth, there are some organizations, however, who are not in complete accord with the position taken by the Public Health Service and the American Medical Association, or at least not in accord with the unqualified endorsement made by the Public Health Service of this program; is that not correct?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. For example, just to indicate one, I have a photostatic copy of page 27 of the New York Times of Monday, April 23, 1951, which says in part as follows:

> The New Jersey State Board of Health was urged today in a report by water experts "neither to promote nor discourage communities" from introducing artificial fluorination of public water supplies as a preventive of dental caries.
>
> The report was made by the trustees of the New Jersey section of the American Water Works Association, which had appointed a special committee to analyze the controversial problem.
>
> While conceding, with some reservations, that fluorine is a deterrent to dental caries, the report said its use as a mass medication had "far-reaching physiological implications and would establish the precedent for the future treatment of water supplies as a cure-all for other deficiencies."
>
> Alternative media for applying fluorine was recommended for exploration, including salt tablets and bread. The processing of water supplies with the chemical was termed "costly and inefficient with 99.5 percent of the chemical and treatment effort wasted."

It concluded by saying as follows:

> The trustees recommended that the State undertake studies and experiments to explore other methods of applying fluorine and that reports of the results be published periodically. It also suggested that studies be directed to determine "possible deleterious systemic effects."

So that apparently, as I indicated before, there are some bodies, some associations of the type of this association, which believe that not enough work has yet been done so that the program should be put in effect all over the country at this time.

Dr. FORSYTH. Would you care to have me comment?

Mr. KLEINFELD. Yes; I certainly would.

Dr. FORSYTH. Well, in the first place this is not mass medication. Controlled fluoridation of communal water supplies is not treating anything. Actually it is putting back into the drinking-water supply fluorides which are found, as I said in my statement, occurring naturally in drinking water.

It does not treat anything, but at the concentration of one part of fluoride to a million parts of water it does prevent to a certain extent new tooth decay. So it does not treat anything, it prevents.

Mr. KLEINFELD. Doctor, is anybody in a position to say quite definitely at this time that the addition of fluorides to drinking water will have exactly the same effect as the presence of fluorine naturally in drinking water?

Dr. FORSYTH. With your permission, Mr. Chairman, I would like to show you some charts that we have from our Grand Rapids study where fluorides in controlled amounts have been added to the water for the past 7 years, and show you some of the results that we have from that study.

I would also like to show you two charts that we have on adults who have lived all their lives on naturally fluoridated drinking-water supplies. I think you could probably get a little better understanding of it if you saw these.

Mr. KLEINFELD. Dr. Forsyth, we will come to those studies, but my question really was not directed specifically at that.

Dr. FORSYTH. All right.

Mr. KLEINFELD. Those controlled experiments, as I understand them, are going on at this time, and I would like to ask you some questions about them fairly soon. But my question was—it may be that

you cannot answer it at this time—whether research has been undertaken to show conclusively that the artificial addition of a fluoride compound to drinking water had exactly the same effect as fluorine contained naturally in the water.

Dr. FORSYTH. Yes.

Mr. ABERNETHY. I did not hear the question, Mr. Kleinfeld.

Mr. KLEINFELD. Whether in every respect the addition of a fluoride compound to a drinking water without fluorine had exactly the same effect as the situation which occurs where fluorine occurs naturally in drinking water.

Dr. FORSYTH. Yes; we have. In setting our base line we used Aurora, Ill., which has 1.2 parts per million of fluorine occurring naturally in the drinking water. So the studies were done there before fluoridation was introduced in Grand Rapids.

Mr. KLEINFELD. Are you familiar with tests which disclose that the use of naturally fluorinated water, with all the constituents therein, will have the same exact effects, good and bad, as where you artificially add a fluoride to drinking water which does not naturally contain fluorine?

Dr. FORSYTH. That is why we studied Grand Rapids, Mich., and when we found after the first 6 years the results were the same, then we felt it was such a wonderful public health preventive we could not withhold it from the public any longer.

We know this: That if you have excessive amounts of fluorides in drinking water, whether it is artificially induced or whether it occurs naturally, that you can have some toxic effect. And we know, too, that the first symptom of high concentrations of fluorides in drinking water supplies—the first sign you find shows up in the teeth as a mottling of the teeth. But you don't get any other effects up to 5 or 8 parts of fluoride per million parts of water. Then you begin to get some deposit in bones.

Mr. KLEINFELD. Dr. Forsyth, another organization which has apparently endorsed the fluoridation of drinking water is the National Research Council.

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. They endorsed it fairly recently, I believe, on November 29, 1951.

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. Are you familiar with the reputation and scientific standing of the members of the National Research Council's Ad Hoc Committee on Fluoridation of Water?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. What kind of a reputation do they have?

Dr. FORSYTH. High.

Mr. KLEINFELD. Highly qualified?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. As you point out in your statement, the National Research Council did endorse the practice of the fluoridation of drinking water. You are familiar with that report?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. I have here, also, the minutes of the first meeting, on April 10, 1951, of the Ad Hoc Committee on Fluoridation of Water Supplies of the National Research Council. Are you familiar with those minutes?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. I would like to ask you about some of the statements which appear in these minutes, which are somewhat puzzling. One of the members of the ad hoc committee stated in part in these minutes, for example, that—

> it had been reported that fluorides accelerated the growth of cancer in mice, and concern had been expressed about the possibility of long-term toxic effects. Waterworks engineers do not feel competent to evaluate these questions, nor to pass on the conclusiveness of the experiments performed on the reduction of dental caries. They, therefore, wished to have the guidance of the National Research Council in these matters.

Has research been done since April 10, 1951, on the question of the growth of cancer in mice by the use of fluorides and the possibility of long-term toxic effects?

Dr. FORSYTH. Just prior to that time, I believe, there was a study going in Texas, at the University of Texas, and we heard unconfirmed reports that mice were developing cancer of the breasts on a low fluoride concentration.

So a cancer specialist and one of our leading dental research workers went down to investigate. We found out that the water concentration was all right, but that both the experimental and the control mice were getting more than 40 parts of fluoride per million parts in their food. So the mice were getting a terrific amount of fluoride in their food intake, but not in their drinking water supply. So it was agreed that their study on cancer in mice was not too sound.

There have been some statistics gathered, also in Texas, where the water has naturally occurring fluoride and where the water is fluoride free, and I do not think we can use this as a criteria because it really is not enough of a difference to be significant—actually in the areas studied they found there was a little less cancer in human beings in the naturally fluoridated water areas. I say such a slight difference isn't significant.

Mr. KLEINFELD. Have you initiated any independent studies on that particular problem—controlled experiments for example?

Dr. FORSYTH. I told you before, we looked into this epidemiologically, beginning over 20 years ago. Both physicians and dentists were sent to Texas and studied individuals who had been on fluoride concentrations of water both at optimum amounts nad at higher concentrations for years and years. So I think from an epidemiological study there hasn't been anything of a public health nature that has had as thorough scrutiny as this particular problem.

Mr. KLEINFELD. Have you made such studies in connection with the use of artificially fluoridated water?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. Where did you make those studies?

Dr. FORSYTH. On animals first before we went to pilot programs.

Mr. KLEINFELD. Have those experiments and results been published?

Dr. FORSYTH. I believe they have. Yes.

Mr. KLEINFELD. Could you give us the reference?

Dr. FORSYTH. Yes, sir.

Mr. FORSYTH. You will do that later?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. In the same minutes, it is stated that—

Dr. Heyroth read excerpts from a report on the fluoridation of water supply and the prophylaxis of dental caries which he presented to the Cincinnati Board of Health, January 26, 1951.

As I understand it, Dr. Heyroth in that report recommended the fluoridation of the drinking water of that city; is that not correct?

Dr. FORSYTH. I am sorry; I didn't hear that.

Mr. KLEINFELD. In the minutes of this meeting of this Ad Hoc Committee of the National Research Council, it is stated that:

Dr. Heyroth read excerpts from a report on the fluoridation of water supply and the prophylaxis of dental caries which he presented to the Cincinnati Board of Health, January 26, 1951.

As I understand it, Dr. Heyroth recommended in his report that the city of Cincinnati fluoridate its drinking water.

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. But in these minutes the following statement is made:

He said that it was important to obtain more data relative to morbidity and mortality in the epidemiological aspects of cancer.

That was said on April 10, 1951. Have further studies been made in view of Dr. Heyroth's statement in respect to the epidemiological aspects of cancer?

Dr. FORSYTH. I believe there is a study going in Texas.

Mr. KLEINFELD. Who is conducting that?

Dr. FORSYTH. I don't know, but I do feel this: That I would challenge anybody to show any evidence that controlled amounts of fluoride, that the amount of one part of fluoride per million parts of water would cause any harmful effects on any human being.

Mr. KLEINFELD. Yet, Doctor; the surprising thing about that is that these gentlemen who, you stated, are real experts in this field, and who apparently, or some of them at least, have recommended the fluoridation of water, do make these statements as to further subjects, fairly important subjects, which they say should be investigated.

Dr. FORSYTH. Most of these studies, if you notice, have been made on higher concentrations of fluorides running 5 to 8 parts or more.

Mr. KLEINFELD. I do not make myself clear. I mean these people like Dr. Heyroth—he said it was important to obtain more data relative to morbidity and mortality in the epidemiological aspects of cancer. He said that on April 10, 1951. Now he said that notwithstanding the experimental work which you have indicated.

Dr. FORSYTH. As I told you before, the studies in Texas on people who have lived there all of their lives on naturally fluoridated drinking water have not shown any increase in cancer.

Mr. KLEINFELD. Of course, there again, we are talking about water with fluorine naturally present, and we are talking not about clinical personal studies, we are talking about so-called epidemiological studies.

Dr. FORSYTH. We are talking about the same concentrations of fluoride, whether it occurs naturally or whether it is returned to the drinking water supply.

Mr. KLEINFELD. Then why are these people concerned, Doctor?

Dr. KNUTSON. May I answer that question?

The CHAIRMAN. I am sorry. We have a witness on the stand. Are you with the doctor?

Dr. FORSYTH. Yes. He is Dr. Knutson, who is directly in charge of the water fluoridation program of the Public Health Service. It is in his division.

The CHAIRMAN. If counsel is agreeable we will put him on.

Mr. KLEINFELD. Surely.

The CHAIRMAN. I think you had better be sworn first, Doctor.

Your name and address?

Dr. KNUTSON. John W. Knutson, United States Public Health Service, Washington 25, D. C.

(The oath was administered by the chairman.)

TESTIMONY OF JOHN W. KNUTSON, D. D. S., DIVISION OF DENTAL PUBLIC HEALTH, PUBLIC HEALTH SERVICE, FEDERAL SECURITY AGENCY

Dr. KNUTSON. The epidemiological evidence which the doctor requested be obtained has been obtained. Comparative studies have been made on the cancer incidence and the cancer mortality rates of San Francisco and Denver. Denver has a natural fluoride concentration in their water supply, that has been in their water supply for 50 to 60 years, of one part per million. The water supply of San Francisco is fluoride-free. The cancer mortality rates, as Dr. Forsyth indicated in these previous studies, were slightly higher in San Francisco than they were in Denver, Denver having one part per million of fluoride in the water supply.

Comparative studies have been made of cities in Wisconsin, those having fluoride concentrations of one part per million and more as compared with cities which have fluoride-free waters, and here too, in every case the rates were slightly higher in communities where the water supply was fluoride-free.

So that this gentleman's question has been answered between the time the question arose and the time the National Research Council endorsed fluoridation.

Mr. KLEINFELD. Doctor, has the Public Health Service conducted actual controlled studies on the problems to which we referred, with artificially fluoridated water?

Dr. KNUTSON. You mean cancer control?

Mr. KLEINFELD. Cancer control, for example. With artificially fluoridated water.

Dr. KNUTSON. In the human population?

Mr. KLEINFELD. Any experiment, any controlled experiment, on human beings, or on animals.

Dr. KNUTSON. No, sir.

Mr. MCDONOUGH. Just a minute, Mr. Counsel. You mean that the fluorine in the water in Denver was a natural fluorine, and that the studies made in Denver and San Francisco were on fluorine that was found naturally in the water?

Dr. KNUTSON. Yes, sir.

Mr. MCDONOUGH. And that you know of no experiments or any studies being made where fluorine has been mechanically added to the water supply?

Dr. KNUTSON. I think it should be clear that the controlled addition of fluoride to water supplies that has been in operation for a period of only 7 years, not long enough to present any—certainly there has

been no evidence observable that it has had any deleterious effects or harmful effects on the population in those communities. I do not think it would be fair to say that controlled fluoridation has gone on long enough to study carefully the effects on cancer incidence. There have certainly been no observable effects thus far.

Mr. McDONOUGH. You have observed that the addition of fluoride mechanically into the water supply has been beneficial?

Dr. KNUTSON. Yes, sir.

Mr. McDONOUGH. According to Dr. Forsyth's testimony, to the teeth of the people there?

Dr. KNUTSON. That is correct.

Mr. KLEINFELD. You say that these controlled experiments, these pairs of cities, one of which is fluoridating and one of which is not fluoridating the water supplies, have been going on for about 7 years?

Dr. KNUTSON. That is correct.

Mr. KLEINFELD. Do you believe that is a long enough period of time in which to judge the possible toxic effects on people?

Dr. KNUTSON. From a chemical standpoint, there is no basis for assuming that a fluoride concentration of one part per million added acts any different physiologically than when it occurs naturally in the water supply. The source is the same. It comes from rock phosphate.

Mr. KLEINFELD. Why, then, are we carrying on these controlled experiments, such as at Newburgh and Kingston, if you are satisfied that the results from the use of artificially fluoridated water are exactly the same as where fluorine is present naturally in the water?

Dr. KNUTSON. To have absolute proof, otherwise the question can always be raised—have you actually done it?

Mr. KLEINFELD. So we don't have actual positive proof with respect to artificially fluoridated water?

Dr. KNUTSON. Yes; we have. These studies have run long enough so that comparison can be made of the findings in the 6- and 7-year-olds, and younger children, with the findings in children of the same age on fluoride-free water.

Mr. KLEINFELD. Are you talking about helping to prevent dental decay or toxic effects?

Dr. KNUTSON. Both.

Mr. KLEINFELD. On all segments of the population?

Dr. KNUTSON. The studies have been largely concerned with pediatric studies.

Mr. KLEINFELD. Not with possible difficulties in the middle-aged and older groups?

Dr. KNUTSON. These fluoridation studies have been concerned wtih the children and not the adults; that is correct.

Mr. KLEINFELD. Is it not true, Doctor, that often—at least it has so been testified before this committee—it takes 10, 20, or 30 years for cancer to develop?

Dr. KNUTSON. Yes.

Mr. KLEINFELD. From exposure at previous times?

Dr. KNUTSON. I believe that is so.

Mr. KLEINFELD. Doctor, again in discussing these minutes, it is stated that one of the members of the ad hoc committee said—

he could see no danger from direct effects of fluoridation, but he thought it important to watch for subtle changes. He asked if an attempt had been made to study these effects in cities with fluoridation of water supply. Dr. Heyroth,

another member of the ad hoc committee, said that such studies had not as yet been made.

Since April 1951, have studies been made with respect to the possible subtle changes caused by the effects of the artificial fluoridation of drinking water?

Dr. KNUTSON. Not since that time. They have been going on during the entire period that controlled fluoridation has been in operation.

Mr. KLEINFELD. But these gentlemen apparently felt that further studies should be made. Is that not correct?

Dr. KNUTSON. Apparently so.

Mr. KLEINFELD. In the minutes of the ad hoc committee, another participant stated that a large amount of study has been given to this subject, but that—

There are certain areas in which difficulties not yet seen should be explored: (*a*) In the aged; (*b*) in individuals with renal involvement.

That means kidney disorders, sir?

Dr. KNUTSON. Yes.

Mr. KLEINFELD (reading):

(*c*) Experimentation in regions where individuals eat a great deal of fish.

Has a large amount of study been given to the effects of the artificial fluoridation of drinking water on people in their 50's, 60's, and 70's?

Dr. KNUTSON. Studies have been conducted which have been concerned with the effects of fluorided drinking water, naturally fluorided drinking water, on adults; yes.

Mr. KLEINFELD. Not with artificially fluoridated water?

Dr. KNUTSON. No.

Mr. KLEINFELD. And have the studies which have been conducted as to the effect on the older groups of the population of naturally fluoridated drinking water been published?

Dr. KNUTSON. They have, yes.

Mr. KLEINFELD. Could you give us a reference to that later?

Dr. KNUTSON. Yes; we will supply that.

Mr. KLEINFELD. And have those studies with naturally fluoridated drinking water been concerned with the possible effects of the ingestion of fluorine on people with some kidney ailment?

Dr. KNUTSON. Not as an individual group. Population studies have been made, just as comparative studies were made on cancer incidence and prevalence of other diseases—nephritis, which is a kidney disease—and again the prevalence of nephritis in communities with fluoride-free water as compared with communities where the water contained one or more parts per million, was higher—higher in the fluoride-free communities. Slightly; not what we would consider a significant difference. There is certainly no indication whatever that people who lived on fluoridated water had any greater risk of dying from nephritis than those who lived in communities where water was fluoride-free.

Mr. KLEINFELD. These studies were not clinical personal studies, were they, on particular persons over considerable periods of time?

Dr. KNUTSON. No; they were not; they were studies of the vital statistics for these different communities.

Mr. KLEINFELD. The report of the National Research Council said in part:

> A radiologic survey at Bartlett, Tex., where the water contains 8 parts per million, revealed an increased bone density not associated with functional impairment in 11 percent of those examined, but roentgenologic examinations of a limited number of persons living in areas where the water contained 1.2 to 3 parts per million, revealed no evidence of fluorosis.

Is that the type of project or study to which you have referred?

Dr. KNUTSON. That is the type; yes.

Mr. KLEINFELD. In other words, only in a limited number of persons; is that correct?

Dr. KNUTSON. The total data is not limited. Each individual consideration may have been limited, but there have been several studies of that nature.

Mr. KLEINFELD. Epidemiological studies?

Dr. KNUTSON. That is correct.

Mr. KLEINFELD. But no particular study; no clinical personal study of a considerable number of persons?

Dr. KNUTSON. Epidemiological studies are in most cases made up of studies of individuals and the report of findings in the aggregate for the group.

Mr. KLEINFELD. In epidemiological studies you watch the group as a whole. Is that not so?

Dr. KNUTSON. That is right.

Mr. KLEINFELD. For example, assume you have a group and are feeding the group fluoridated water. You are going to try to find out how much less dental decay is present in this group as a whole. Is that not correct?

Dr. KNUTSON. Yes, but it should be clear that a group finding is a report of the findings of studies of individuals and grouping them together.

Mr. KLEINFELD. Well, let me put it another way. These group studies do not show, do they, when any one particular person or two particular persons may have good of bad effects? It reaches a conclusion based on what happens to the population as a whole.

Dr. KNUTSON. That is true.

Mr. KLEINFELD. In other words, in an epidemiological inquiry all observations are related to the group. In a clinical study the observations remain related to the particular individuals under study. Is that not a sound statement?

Dr. KNUTSON. I would disagree with that statement. I do not think it is. A detailed clinical examination of each individual in a population group may be made and the analysis reported on the basis of the results for the group.

Mr. KLEINFELD. But in making these epidemiological studies you are not particularly interested in John Doe or John Smith, you are not watching him very closely. Of course he is part of the population group, but you are interested in what happens to that population group. Is that not correct? For example, you would want to know whether there is a greater or lesser incidence of cancer or dental decay in that group, but you would not be watching closely each particular person in that group. Is that not so?

Dr. FORSYTH. Might I give you an example?

Mr. KLEINFELD. Yes.

Dr. FORSYTH. Of what we did in Grand Rapids. Before we started fluoridating we examined individually every school child in Grand Rapids, roughly about 30,000 of them. Now we did not have the money or the men to go back and examine 30,000 each year, but we took what investigators feel is a reasonable percentage each year when we went back. And that ran to about eight to ten thousand of them. We picked them out in the various age groups so we were getting a repeat on individuals, and you are also getting some new individuals. So that we had an individual study on every child before the Grand Rapids project started.

Mr. KLEINFELD. What I read before and will read again, is this, and apparently you disagree. I said:

> In an epidemiological inquiry all observations are related to the group. In a clinical study the observations remain related to the particular individuals under study.

That comes from a paper entitled "Some General Epidemiological Considerations" by H. Trendley Dean, of the National Institute of Health, United States Public Health Service.

Dr. KNUTSON. That is a sound general statement; there is no question about that.

Mr. KLEINFELD. Do you disagree with it or agree with it, sir?

Dr. KNUTSON. The point I want to make clear is that if we get one objectionable case of mottled enamel in a community, even if it involved the examination of a thousand children, that would be too much fluoride. Now the findings reported on a group basis would show that one out of a thousand got mottled enamel, only one individual, yet that result would be objectionable from a public health standpoint. I merely wanted to make that point clear.

Mr. KLEINFELD. Well, the point I wanted to make clear is that you were not examining particular individuals to determine whether each was hurt or harmed or watching what happened to him. You were watching the results as a whole—you were conducting these epidemiological studies, and, as Dr. Dean said, they are related to the group as a whole.

Dr. KNUTSON. That is true.

Mr. KLEINFELD. Have you conducted experimental work with respect to the effects of the artificial fluoridation of the water in regions where individuals eat, for example, a great deal of fish, as suggested?

Dr. FORSYTH. I would say Grand Rapids is an area where certainly they are close to a good fish supply. I am not sure how many fish each individual in Grand Rapids eats. I doubt if anybody could tell you that.

Mr. KLEINFELD. That was in an area where there is artificial fluoridation of the water?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. One of the men participating in the ad hoc committee meeting did suggest that such a study be made, so apparently he thought it of some importance at that time.

The CHAIRMAN. Let me interrupt there. Doctor, will you explain to us what you mean by mottled condition of the teeth?

Dr. FORSYTH. With higher fluoride concentrations, you get a discoloring of the teeth. The higher it is—the more brown stain effect,

and finally you can get to the point where the enamel is so affected it will be misssing in areas. This occurs at 14 or 15 parts of fluorine per million parts of water.

The CHAIRMAN. What is that doing—eating away the enamel?

Dr. FORSYTH. It is a discoloration of the enamel.

The CHAIRMAN. Is it similar to a tobacco stain on your teeth?

Dr. FORSYTH. We do not have any photographs with us, I am sorry, to show you what a bad case of mottled enamel looks like. We have some.

Mr. ABERNETHY. Does it have depth to it or does it simply appear on the surface of the enamel and is removable?

Dr. FORSYTH. It is in the surface coating of the teeth. The crown of the tooth, the part you see, has a thin coating of enamel. That is the hard part of the tooth.

Mr. ABERNETHY. Does the mottling go through the enamel?

Dr. FORSYTH. Yes, into the enamel.

Mr. ABERNETHY. It has depth, something which does not just appear on the surface?

Dr. FORSYTH. That is right.

Mr. ABERNETHY. And is not something that is removable, let us say, with a high cleansing material of some kind?

Dr. FORSYTH. That is correct.

The CHAIRMAN. Ordinary scaling would not take it off?

Dr. FORSYTH. No, sir.

Mr. MCDONOUGH. When it is discovered, can you treat the individual to remove it? Can you treat him clinically to remove it?

Dr. FORSYTH. I do not feel qualified to answer that.

(There was discussion off the record.)

Mr. ABERNETHY. In your judgment it is a permanent discoloration of the teeth?

Dr. FORSYTH. That is right.

Mr. MCDONOUGH. Except for the discoloration, what other effects does it have on the individual? Is it a cosmetic question or is it a question of good appearance primarily?

Dr. FORSYTH. Primarily an esthetic appearance.

Mr. MCDONOUGH. In other words, the mottling does not injure the individual at all?

Dr. FORSYTH. No, not the mottling of itself.

Mr. MCDONOUGH. And when you find mottling on the teeth, do you find that the individual is affected in any other part of his system as a result of absorbing the fluorine from the water?

Dr. FORSYTH. If he had high enough concentrations of fluoride he could get some deposit in the bones. You might even get fragility of bone if it was a very high concentration.

Mr. ABERNETHY. Does mottling actually injure the tooth? Does it tend to shorten the life of the tooth?

Dr. FORSYTH. Other than from an esthetic appearance; no. If you get a high enough concentration you could get an interference with laying down of enamel so you wouldn't get enamel on the tooth.

Mr. ABERNETHY. What it amounts to then is simply a discoloration of the teeth?

Dr. FORSYTH. Primarily.

Mr. ABERNETHY. I see. We were confused and decided to inquire.

Mr. KLEINFELD. Doctor, I am a little confused myself, because besides this esthetic factor you mentioned, I have read in reports that if there is a mottling of teeth, more than a very minor mottling, it is going to make the problem of filling cavities, if any, which occur in those teeth, very, very difficult. Is that not true?

Dr. FORSYTH. Why?

Mr. KLEINFELD. I am asking you, is it true? I do not know. I am not qualified.

Dr. FORSYTH. I don't know why it would.

Mr. KLEINFELD. What is your answer to that?

Dr. FORSYTH. I don't know why it would.

Mr. KLEINFELD. Do you know of any reports to that effect in the literature?

Dr. FORSYTH. I don't recall any. Do you?

Dr. KNUTSON. Except in very high concentrations is the enamel affected.

Mr. KLEINFELD. Suppose you had high concentrations, what would happen to a tooth which became highly mottled, with respect to filling cavities that might occur? Would that be a problem?

Dr. KNUTSON. It might be; yes.

Mr. MCDONOUGH. Would the tooth become more brittle?

Dr. KNUTSON. That is correct; yes. The enamel is more fragile and chips more readily.

Mr. KLEINFELD. Doctor, we mentioned briefly, a little while ago, the Cincinnati report on the fluoridation of the water supply in the prophylaxis of dental caries. That was prepared and submitted by Dr. Heyroth, was it not?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. Who came to the conclusion that the fluoridation of the water of that city should be carried into effect?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. Yet, in his report, there are several statements on which I should like to get your views. This again was in 1951. Dr. Heyroth said this:

> About 1946, workers of the United States Public Health Service expressed the opinion that fluoridation should not be undertaken until epidemiologic data comparable in reliability to those secured in regard to the incidence of caries and mottled enamel had been obtained on the health of old people who had lived for long periods in areas of known high and low fluoride concentrations in the drinking water. Unfortunately, such data have not been provided, except to a very limited extent.

Is it not important that such data should be provided to a greater extent, Doctor?

Dr. KNUTSON. Yes. As I indicated previously, those data to our satisfaction have been provided from the studies of mortality rates and morbidity rates for communities that have naturally fluorided water as compared with communities that have fluoride-free drinking water.

Mr. KLEINFELD. Apparently Dr. Heyroth wasn't quite as satisfied as the Public Health Service in that respect, because he says: "Unfortunately such data have not been provided, except to a very limited extent."

So apparently there is some difference of opinion on it. Is that not true, Doctor?

Dr. KNUTSON. Apparently there is.

Dr. FORSYTH. I think, Mr. Chairman, you would find all public health procedures that have been brought out in the past have had this same sort of thing come up. I think if we go back in history you will find when people advocated the chlorination of water supplies, certain people wanted to hold off and do more studies on it and so forth. You will find that all public health procedures which have been good for people have had opposition.

I happen to have lived in a community in Oklahoma that actually passed a city ordinance against the pasteurization of milk.

Mr. KLEINFELD. Dr. Heyroth is not opposed to it, he is in favor of it.

Dr. FORSYTH. Yes.

Mr. KLEINFELD. And the people whom I mentioned in the National Research Council were in favor of it, as you are, and yet they raise these questions. It seems to me that is a very puzzling thing.

Dr. FORSYTH. I believe this: We should continue going back each year and study Grand Rapids' population as we have been doing. We can even go back to Muskegon, although we have lost our control city there. They felt they wanted the water fluoridated, and so it is being fluoridated, and so we have lost it as a control. But we certainly want to go back each year and do re-examinations.

Mr. KLEINFELD. In the very first page of your statement, Doctor, you refer to a statement before the Senate Subcommittee on Appropriations on April 24, 1951, by Dr. Scheele, and you quote him as saying:

> During the past year our studies progressed to the point where we could announce an unqualified endorsement of the fluoridation of public water supplies as a mass procedure for reducing tooth decay by two-thirds.

Dr. FORSYTH. That is correct.

Mr. KLEINFELD. Does an unqualified endorsement mean that you have no question whatsoever of the effect of the fluoridation of water on any segment of the population?

Dr. FORSYTH. That is correct.

Mr. KLEINFELD. And when did the Public Health Service first recommend the fluoridation of public drinking water?

Dr. FORSYTH. A little over a year and a half ago, I believe. Actually June of 1950.

Mr. KLEINFELD. June of 1950?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. Dr. Heyroth's report also stated:

> McClure found that the number of fractures reported by 1,450 high-school boys and by 1,700 draftees bore no relation to the fluoride content of the water of the areas in which they had lived. Furthermore, careful pediatric observations, including X-ray studies, on the children in the Newburgh experiment have failed thus far to demonstrate any deviation from normal skeletal maturation and no increases in radiological density. However, data obtained on children or young adults have little bearing upon the problem of chronic fluorosis in the aged.

Do you agree with that, sir?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. What does chronic fluorosis in the aged mean?

Dr. FORSYTH. Actually fluorosis is a term applied to the mottled enamel. Chronic endemic fluorosis is the correct name for the mottled enamel.

Mr. KLEINFELD. Does it refer also to the possible effects on people who are getting older and whose bones may be becoming more brittle?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. Are you satisfied that experiments which have been conducted in, for example, these controlled cities have demonstrated beyond any reasonable doubt that older people whose bones may be becoming more brittle are not affected at all by the addition of fluoride to drinking water?

Dr. FORSYTH. Our experiment has only run in Grand Rapids 7 years, as we told you previously, but studies have been made in Colorado Springs on people who have lived on naturally fluoridated water all of their lives.

Mr. KLEINFELD. But with respect to artificially fluoridated water, you say the experiments are not over yet; is that not correct?

Dr. FORSYTH. That is correct.

Mr. KLEINFELD. Yet you issue an unqualified endorsement?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. Again, in the Heyroth report, the following statement appears:

> The question of the effect of water containing one part per million upon patients with severe impairment of kidney function requires special consideration in view of the fact that radiologic evidence of chronic fluorosis has been found in two persons with severe kidney disease who died at the early ages of 22 and 23 years, respectively. It is very likely that the life expectancy of persons with a degree of functional impairment of the kidney great enough to increase significantly the rate of storage of fluoride would be too short for skeletal damage involving functional impairment to become manifest. However, this question has not been adequately studied.

There, too, do you disagree with Dr. Heyroth's statement that the question of impairment of kidney function has not been adequately studied?

Dr. FORSYTH. I would say it had in naturally fluoridated water areas, definitely.

Mr. KLEINFELD. He continues:

> It is highly desirable that in a region where the water contains one part per million determinations of the ability of the kidney to excrete fluorides be made on large numbers of hospitalized patients with chronic kidney disease of various types and degrees of severity, and that the results be compared with those obtained upon healthy persons.

Has such actual clinical work been done?

Dr. FORSYTH. I don't know of any. Do you?

Dr. KNUTSON. The studies relating to kidney diseases have been done. However, it must be understood that if you have a kidney disease, which results in retention, that the retention itself brings about the deleterious effects on the kidney, and that there is no evidence that fluoride accentuates that.

We are talking about a very severe condition which varies, which can become very severe and cause death. And to say that the fluoride in the water supply, at one part per million—let's put it this way: There is no evidence whatsoever that one part per million of fluoride in water supplies brings about an exaggeration of the condition.

Mr. KLEINFELD. Is there evidence that it does not?

Dr. KNUTSON. Direct evidence that it doesn't? No, I wouldn't say that there is.

Mr. KLEINFELD. Again I might mention that this statement is made by Dr. Heyroth, who approved the fluoridation of the Cincinnati water supply, and who apparently is an authority on this subject, is he not?

Dr. KNUTSON. Yes, he is an authority. But again there is no reason for believing under these circumstances that one part per million of fluoride would bring about an exaggeration of these condtions. There is no reasonable ground for believing that.

Mr. KLEINFELD. Can we definitely say that unless we examine hospitalized patients, who are suffering from serious kidney disorders, from a clinical viewpoint?

Dr. KNUTSON. I would say "Yes," that there would be no reasonable basis for assuming that one part per million of fluoride would exaggerate the condition.

Mr. MCDONOUGH. May I interrupt for a moment? Is there much difference between the addition of fluorine to water to prevent tooth decay, and milk or anything that contains a large amount of calcium to prevent tooth decay? Isn't the dentine on teeth largely a calcium compound?

Dr. FORSYTH. Well, calcium is one of the ingredients of dentine, yes.

Mr. MCDONOUGH. It is predominantly calcium, isn't it?

Dr. FORSYTH. Calcium compound, yes.

Mr. MCDONOUGH. 90 percent of it. And isn't there quite a similarity between fluorine and calcium as far as their protective effect to the dentine?

Dr. FORSYTH. Well, the calcium helps build up the body of the tooth; it does not protect against tooth decay. That is just one of the ingredients of the tooth.

Mr. MCDONOUGH. Don't the milk people say because there is a lot of calcium in milk, that that is one way to assimilate calcium in the system to prevent decay?

Dr. FORSYTH. That is to help make healthy bones and healthy teeth.

Mr. MCDONOUGH. Right.

Dr. FORSYTH. But the calcium itself does not protect the tooth against tooth decay.

Mr. MCDONOUGH. Would the addition of fluorine to water create a calcium fluorine in dentine? Is there a chemical combination in the dentine?

Dr. KNUTSON. That combination probably is calcium fluoride or fluorapatite.

Mr. MCDONOUGH. What is that—apatite?

Dr. KNUTSON. That is correct, yes.

Mr. MCDONOUGH. I don't understand that term applied to that.

Dr. KNUTSON. The enamel of the tooth is hydroxy apatite, and when fluoride is added parts of it become fluorapatite.

Mr. MCDONOUGH. Let me ask this: Has it been determined chemically in the analysis of dentine of the tooth that it becomes a calcium fluoride when there is an extensive amount of fluorine in drinking water—a mottled tooth, for instance?

Dr. KNUTSON. Precisely what form the fluoride exists in the enamel and in the dentine has not been determined. It has been demonstrated that the fluoride content is increased in the total substance of the

enamel and in the dentine, that there is more fluoride in these substances in persons who drink fluorided drinking water.

Mr. McDONOUGH. Is it known that there is any fluoride accumulation in teeth where there is no fluoride in the water?

Dr. KNUTSON. Yes. All tooth enamel and all tooth dentine contains some fluorine. Many foods, you see, contain fluorine. Fish is high in fluoride, tea is high in fluoride, spinach has a considerable amount of fluoride. So that fluorine is a normal constituent of the average American diet.

Mr. McDONOUGH. And does fluorine have a similar effect on building up the bone structure of the human being as the addition of calcium?

Dr. KNUTSON. It is not necessary for the build-up of bone structure. There is fluorine in bone, absorbed from foods and from drinking water, if the drinking water contains fluoride.

Mr. McDONOUGH. What I am getting at is this—isn't there a similarity between fluorine and calcium insofar as building up the dentine of the teeth or the bone structure of the human being?

Dr. FORSYTH. They are essential parts. There would be varying amounts, but they are essential elements in all the structures of our body. And fluorine is one of the essential elements of tooth structure as well as of bone. So is calcium.

Mr. McDONOUGH. So in making pathological studies of individuals who may be affected by the fluoridation of water, you would have to check his diet to find out what else he is eating and if he obtains larger amounts of fluorine than he did through the water. In other words, if you wanted to study what effect the addition of fluorine to a human may have on his kidneys, or on any other vital part of his body or as to cancer, you would have to find out what food he is eating that has flourine in it in addition to the fluorine he obtains from the water. Is that not true?

Dr. FORSYTH. Yes, sir.

Mr. McDONOUGH. All right.

Mr. KLEINFELD. Doctor, the kidneys are very important, are they not, in excreting fluorine which may be ingested into the body?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. I think that was pointed out as far back as 1946 by F. J. McClure of the National Institute of Health. He said, for example, in an article entitled "Non-Dental Physiological Effects of Trace Quantities of Fluorine," and I quote:

> The hazard of cumulative toxic bone fluorosis surrounding most domestic fluoride waters now seems greatly reduced by the observation that a remarkably efficient excretion of fluorine is normal kidney function.

Is that correct?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. If we have certain portions of the population who do not have a normal kidney function, who are suffering from some kidney disorder, it is quite likely, is it not, there would not be an efficient excretion of fluorine as far as those people are concerned?

Dr. FORSYTH. Not only of fluorine, but it would be of any other substance.

Mr. KLEINFELD. That is right. And how about fluorine?

Dr. FORSYTH. I say of anything that the kidney might happen to be trying to excrete, whether it was fluorine or anything else.

Mr. KLEINFELD. But we are engaged in a policy of adding fluorine to drinking water which these people must consume, must they not?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. A last statement from Dr. Heyroth, who wrote this authoritative report for the city of Cincinnati, was:

> In any event, the risk that such patients might be harmed by the fluoridation of water appears to be small in comparison with the dental benefits to be obtained. It should be possible for physicians who have the care of patients with severe chronic kidney disease to recommend the use of imported fluoride-free water should this be necessary.

Are you in accord with that point of view?

Dr. FORSYTH. Well, we told you of the studies on the population groups in naturally fluoridated water areas, Wisconsin and San Francisco, which did not have fluoride in the drinking water, that there was no difference in kidney disease, as well as cancer, in the two cities, except actually in the nonfluoridated water supply there was a little more cancer than there was in the fluoridated water supply.

Mr. KLEINFELD. Then apparently you disagree with Dr. Heyroth who believes, notwithstanding his endorsement of the program, that if you have a person—and there are some in the population of the country, I assume—who is suffering from severe chronic kidney disease, that person should be given fluoride-free water.

Dr. FORSYTH. Well, I think that is up to the physician handling the case.

Mr. KLEINFELD. What do you think?

Dr. FORSYTH. Not being a physician, I don't feel that I am qualified to say.

Dr. KNUTSON. Certainly there is no evidence that one part per million, as indicated earlier, would exaggerate this kidney condition.

Mr. KLEINFELD. Well, that, of course, is exactly what Dr. Heyroth is discussing. And to look at it conversely, Dr. Heyroth is saying, as I understand it, that we do not have evidence that it would not hurt these people. Now isn't that important from the physician's viewpoint?

Dr. KNUTSON. Yes, sir.

Mr. KLEINFELD. Doctor, have there been any studies to determine the approximate amount of water that is normally drunk by the different age groups of our population?

Dr. FORSYTH. Yes. I would say on the average of about 1 liter per day.

Mr. KLEINFELD. That is about a quart?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. Isn't that, however, a very variable factor, particularly among children, depending upon the amount of exercise they may do on a particular day or on the time of the year?

Dr. FORSYTH. It is variable also according to the climate.

Mr. KLEINFELD. If a child were to drink 2 liters of water a day, how much in the way of fluoride would he get into his system?

Dr. FORSYTH. He would get about 2 milligrams. But I think if you will recall in my opening statement to you I said that even at one part of fluorine per million parts of water, to get a lethal dose from it you would have to drink 400 gallons at one sitting. So that 2 liters or even a gallon would be of no consequence in daily consumption.

Mr. KLEINFELD. Well, are you saying that he might then be taking 2 milligrams into his system every day?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. And are you satisfied that that amount would not cause any mottling of the teeth, for example, over a considerable period of time?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. Has the factor of individual susceptibility been considered in that connection, Doctor?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. Well, you mean that there are no individuals who, because of a particular susceptibility, may be more prone to get mottling of the teeth or some other hurtful effect?

Dr. FORSYTH. Not at that concentration.

Dr. KNUTSON. For the record, I think it should be perfectly clear in this questioning that it was first established that there is no difference between adding the fluoride to the water supply under controlled conditions and having it occur naturally in the water supply. So that the questions relating to—have these findings been observed in the controlled studies as versus natural studies—is ruled out on the basis of that conclusion. And the findings should be similar.

Now in communities where they naturally have one to one and one-half parts per million, extensive studies have demonstrated that objectionable mottling does not occur, and in those communities we have wide variation, too, in the amount of water that individuals will drink. But in that wide variation there is no objectionable mottling of the teeth.

Now then, there is no reasonable basis for saying that variation in water consumption would be different in a community on a fluoride-free water than in one which has a naturally fluorided water.

Mr. KLEINFELD. Doctor, you seem to be talking from the basis of what has been gathered and learned from populations which have been drinking naturally fluoridated water, water in which fluorine occurs naturally. Yet you are not belittling the importance of the studies which are being carried on in these controlled cities, are you? They were undertaken for that reason.

Dr. KNUTSON. No, indeed.

Mr. KLEINFELD. You want to know what happens, do you not, when large populations are or are not given water which contains a fluoride? Isn't that correct?

Dr. KNUTSON. That is true. But again the judgment is on the basis of the laboratory studies which Dr. Forsyth referred to, and on the basis of operation of these controlled studies, and on the results from those studies, and leads to the conclusion that the effect of the fluoride in controlled fluoridation is the same as in communities where it occurs naturally. There is no reason whatever to believe that they operate differently in any way whatsoever.

Mr. KLEINFELD. You are positive of that?

Dr. KNUTSON. Yes, indeed.

Mr. KLEINFELD. I have a reprint here from the American Journal of Public Health, Volume 40, No. 6, 1950, entitled "The Newburgh-Kingston Caries Fluorine Study." This is one of these experiments conducted in two cities. As I understand it, the water supply of Newburgh has been fluoridated with 1 part per million of fluoride, and the water of Kingston has not been fluoridated; is that correct?

Dr. KNUTSON. That is correct.

Mr. KLEINFELD. This, as I understand it, is the official report. It is written by David B. Ast, Sidney B. Finn, and Isabel McCaffrey, on the dental findings, and Edward R. Schlesinger, David E. Overton, and Helen C. Chase, on the pediatric aspects—a preliminary report. Are you familiar with that, Doctor?

Dr. FORSYTH. Yes, but there is also a later report I have available here fo you. It is our library copy. It is by the same group of people.

Mr. KLEINFELD. Is that the dental report or the pediatric report?

Dr. FORSYTH. Dental.

Mr. KLEINFELD. In connection with the pediatric aspects of this controlled experiment conducted in Newburgh and Kingston, let me read you what these people say on the pediatric aspects of the Newburgh experiment, where 1 part per million of fluoride was added to the drinking water of that city. They say in part:

> Other special studies are being conducted or planned to answer special questions in connection with the Newburgh-Kingston study. A study is well under way, in cooperation with Barnett and McNamara at the New York Hospital in New York City, to determine the mode of excretion of fluoride in the urine of children having impaired renal function compared with a group of children of the same age with normal renal function. Another study being planned will attempt to utilize objective quantitative methods for the determination of bone density of children in Newburgh and Kingston.

So that these people who are conducting this Newburgh-Kingston caries fluorine study say that a study is now going on to determine the mode of excretion of fluoride in children who have a normal kidney function and those who have an impaired or abnormal kindney function. Isn't that an important thing to study, Doctor?

The CHAIRMAN. What percentage of the population would you say might have kidney trouble?

Mr. KLEINFELD. I do not know. Maybe the doctor could tell you. Do you know, Doctor?

Dr. KNUTSON. No, I can't. I believe it is the third most important cause of death.

Mr. KLEINFELD. Are there some children with impaired kidneys?

Dr. KNUTSON. Oh, yes, indeed. We could supply that for the record.

The CHAIRMAN. I mean if there were a large number of children or a large number of people that did suffer from it, then it might be a most important factor.

Dr. FORSYTH. I believe we could secure the data for you and supply it to the committee.

The CHAIRMAN. I think it would be important.

Dr. KNUTSON. I think it is important to understand the characteristics of science in medicine and dentistry—that we carry on continuous studies to learn more and more. We recognize that knowledge is never absolute in any field.

The CHAIRMAN. We understand.

Dr. KNUTSON. We never know all there is to know about anything.

The CHAIRMAN. We appreciate that, Doctor. We were just discussing that between ourselves.

Mr. KLEINFELD. Yet you made an unqualified endorsement of this process. You said you were positive in this connection, which is one of the most direct and forthwith recommendations I think the committee has ever had. You made no qualifications whatever as to your

endorsement of the fluoridation of drinking water. Is that not correct?

Dr. FORSYTH. That is correct.

Mr. MCDONOUGH. Let me interrupt for a minute. In reading the statement, I find:

> During the past year our study progressed to the point where we could announce an unqualified endorsement of the fluoridation of public-water supplies as a mass procedure for reducing tooth decay by two-thirds.

Well, that being such a conclusive statement, should not it be more specific?

You say: "Fluoridation of public-water supplies." You further say that fluoridation of public water should not exceed one part per million, that that is a safe amount. But in your statement, you don't say the fluoridation of one part per million of public-water supply, you say fluoridation.

Dr. FORSYTH. Yes, we do.

Mr. MCDONOUGH. Not in your quotes.

Dr. FORSYTH. Not in the quotes, no.

Mr. MCDONOUGH. Well, fluoridation could mean 10 percent.

Dr. FORYTH. You see actually the safe amount had been set even before fluoridation, at 1½ parts per million in our Public Health water standards. So we don't recommend more than 1 to 1½ parts of fluorine per million parts of water.

The CHAIRMAN. That statement standing alone and unexplained might cause some confusion. Is that right?

Dr. FORSYTH. Yes, but that has been explained.

The CHAIRMAN. I say the statement standing alone.

Dr. FORSYTH. Yes, sir. I see your point.

Mr. ABERNETHY. What he has done is list the conclusions of Dr. Scheele.

Dr. FORSYTH. That is right.

Mr. ABERNETHY. Which evidently were based on just exactly what Dr. Forsyth has incorporated in his statement.

Dr. FORSYTH. That is correct.

Mr. ABERNETHY. To be used under certain methods.

The CHAIRMAN. And we are talking about that taken as an extract.

Dr. FORSYTH. Yes, sir.

Mr. MCDONOUGH. If the press were to take up that statement, and not qualify it by any explanation, it could mean that Dr. Scheele has said before the Senate Subcommittee on Appropriations on May 24 that the fluoridation of public water supplies as a mass procedure for reducing tooth decay by two-thirds is unqualifiedly recommended.

Now as to the areas that do not have fluorine in their water supply, the public generally might say, "What does fluoridation mean—1 part per million, 5 parts per million, 15 parts per million?"

Dr. FORSYTH. As I mentioned in my opening statement, too, in some areas due to difference in climate, such as the hot, dry, arid section of Arizona, we wouldn't recommend one, we would recommend 0.6 parts and, if a community already had, shall we say, 0.4 parts of fluoride per million parts of water in the drinking water supply, we wouldn't recommend the addition of one part, we would recommend addition up to one part, which would mean then adding 0.6 parts. So it varies according to community.

Does that answer your question?

Mr. McDonough. Yes. Of course, you are quoting Dr. Scheele. It is not your testimony.

Dr. Forsyth. No, sir.

Mr. McDonough. It seems to me it might be misconstrued that fluoridation of water could mean any amount of fluorine in the water.

Mr. Kleinfeld. I think they have always limited themselves to about one part per million.

Dr. Forsyth. Yes.

Mr. Kleinfeld. Doctor, on page 2 of your statement, in talking about what the Public Health Service relied upon, you say in part you relied on these pilot programs, one of which was this Newburgh, N. Y., pilot program.

Dr. Forsyth. Yes, sir.

Mr. Kleinfeld. In the official report dated June 1950, of the people who are carrying on this Newburgh pilot program, the concluding paragraph is as follows. And again I say you relied in part, at least, on this pilot experimental study.

> The results thus far in the study have disclosed no deleterious systemic effects from the ingestion of fluoride in drinking water in the dosage employed. It must be emphasized, however, that a longer period of observation is required before final conclusions can be drawn. The possibility of demonstrating cumulative effects of fluoride in the final years of the 10-year study cannot be eliminated at this time. More refined techniques may also be available in the future in studying pertinent aspects of the problem.

So that these people who are carrying on the Kingston-Newburgh pilot experiment say they cannot ignore the possibility of demonstrating cumulative effects of fluoride in the final years of this 10-year study. When will this 10-year study be completed?

Dr. Forsyth. It has now been running almost 7 years, so I suppose they plan to carry on three more years.

Mr. Kleinfeld. Weren't these pilot experiments originally planned on the basis of a certain period? For example, wasn't the Kingston-Newburgh experiment planned originally and set up on the basis of a 10-year study?

Dr. Forsyth. Yes.

Mr. Kleinfeld. Why, then, is it scientifically accurate to reach positive conclusions and make an affirmative recommendation before that period has expired, when these people make statements such as that?

Dr. Forsyth. Well, may I ask you this: Is there any guaranty on any experiment when you start it that it is going to finish at a certain time? What is magic in the figure of 10 that determines how long an experiment should run? That is just somebody's opinion. Sometimes you would want to run experiments twice as long, or you might want to run them for life, and again you might come up with the answer in 1 or 2 or 3 years.

Mr. Kleinfeld. Who picked out the 10-year period?

Dr. Forsyth. Actually both the Public Health Service's study and the Newburgh study were set for a minimum of 10 years—not meaning that either ought to be cut off in 10 years.

Mr. Kleinfeld. As you said yourself, Doctor, you have to set some limits, don't you?

Dr. Forsyth. Yes; you have to have some standards to go by to start.

Mr. KLEINFELD. And the Public Health Service, and I imagine these other interested people, did decide for some reason that 10 years was the period that should be observed?

Dr. FORSYTH. The minimum period.

Mr. KLEINFELD. Minimum period?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. This minimum period has not terminated, has it?

Dr. FORSYTH. No.

Mr. KLEINFELD. Yet you feel you are in a position to state now that you can unqualifiedly endorse the artificial fluoridation of drinking water?

Dr. KNUTSON. As Dr. Forsyth said, a minimum period of 10 years. That didn't mean it would require 10 years to demonstrate conclusively that the same results were being effected by controlled fluoridation as obtained in communities where the water contains fluoride naturally in the optimum concentration.

Mr. KLEINFELD. Well, again, I ask you, What was the purpose of initiating this experiment at all?

Dr. FORSYTH. One of the reasons was that we wanted a minimum of 10 years to study both the effects on deciduous teeth, or baby teeth, and permanent teeth, as they were coming into the mouth.

Now, if you had set 5 years or 6 years as a basis, you would not have picked up any of the permanent teeth except very few of them, possibly, from the study.

Mr. KLEINFELD. Well, Doctor, let's talk about the converse situation. Suppose in one of these pilot experiments after 3 years you got unfavorable results, would you adopt those results, discontinue the experiment, and issue a report saying that the results were unfavorable and that we should discontinue the practice?

Dr. FORSYTH. Actually negative results are sometimes just as important as positive results.

Mr. KLEINFELD. Well, what about the experiment conducted in Ottawa, Kans.? Weren't results reached there after at least 3 years which were unfavorable in nature?

Dr. FORSYTH. I don't recall.

Mr. KLEINFELD. Let me read you something then from volume 30, No. 4, dated August 1951, Journal of Dental Research. There is an article entitled "Fluoridation of Drinking Water," which was reporting the proceedings of the International Association for Dental Research held March 17, 1951. It is entitled "Unfavorable Report From Kansas Community Using Artificial Fluoridation of City Water Supply for 3-Year Period."

Are you familiar with that?

Dr. KNUTSON. Yes; I am familiar with that.

Mr. KLEINFELD. In the last sentence they say this:

> This report is offered merely to demonstrate that the results of the fluoride experiment are not universally favorable. No explanation is attempted, and the test will continue to run its 10-year trial period.

Do you agree that the tests should continue to run for a 10-year trial period before saying that the results which were unfavorable after 3 years should be accepted as final?

Dr. KNUTSON. As I indicated, I am familiar with the report. I was at the meeting at which it was presented. The author of the paper was questioned regarding the conditions of the experiment, and

it was quite clear that the conditions of the experiment, the comparison being made, were not controlled. Different examiners were used; and the findings on caries experience in the second examination, the 3-year examination, were in the judgment of the group quite unrealistic.

Mr. KLEINFELD. Were not different examiners used in conducting the Kingston-Newburgh experiment?

Dr. KNUTSON. Calibrated. What we call calibrated examiners.

Mr. KLEINFELD. Different persons are examining children in Kingston and Newburgh?

Dr. KNUTSON. Using the same standards of examination, thoroughly instructed in the standards of examination.

Mr. KLEINFELD. Are those standards entirely objective, in your opinion?

Dr. KNUTSON. They are adequately objective, I would say; yes.

Mr. KLEINFELD. Did these examiners know from what city the children they were examining came?

Dr. KNUTSON. Yes. However, X-ray studies have been made, X-rays of the teeth, and the analysis was made without the individual making the interpretation of the caries experience knowing. And the analysis indicated that, when the interpreter of the X-rays didn't know what city an individual came from, the results were almost identical with the clinical findings.

Mr. KLEINFELD. Have you gone into the question of the possible effect of the addition of artificial fluoride to water on children who are suffering to some extent from malnutrition?

Dr. KNUTSON. Specifically, no.

Mr. KLEINFELD. The reason I asked was because in the February 1952 issue of the Journal of the American Dental Association, which just came out this month, there is an article entitled "Relation of Endemic Dental Fluorosis to Malnutrition" by Maury Massler, D. D. S., M. S., and Isaac Schour, D. D. S., Ph. D., Chicago. And these people make the following statement:

> Importance of investigations of nutritional status: The data from this and other investigations suggest that malnourished infants and children, especially if deficient in calcium intake, may suffer from the effects of water containing fluorine while healthy children would remain unaffected. It is possible that the small proportion of individuals who show some, though slight, endemic dental fluorosis in communities with only about one part per million of fluorine in the water supply do so because of insufficient intake of calcium or because of disturbances in calcium metabolism.
>
> Thus low levels of fluoride ingestion which are generally considered to be safe for the general population may not be safe for malnourished infants and children. Therefore, the nutritional status must be carefully assessed and guarded in areas with endemic fluorosis. Nutritional studies should be included in any comprehensive program of fluoridation of water, with special attention to chronically ailing infants and children.

Have such studies been carried on?

Dr. KNUTSON. Not specifically. But I would want to point out again that the findings in communities where they have 1 to 1.5 parts per million of fluoride do not reveal fluorosis of an objectionable character. And the population in those cities ordinarily has some children who are malnourished, and in spite of that those children on examination do not show objectionable fluorosis.

Mr. KLEINFELD. Are you in a position to say that examinations were made specifically of children who were known to be malnourished?

Dr. KNUTSON. No; as I stated at the beginning, not specifically for that purpose.

The CHAIRMAN. Off the record.

(There was discussion off the record.)

The CHAIRMAN. Since these gentlemen are in the city and will be able to return, under those circumstances the committee will stand adjourned subject to call.

(Whereupon, at 12 noon, the committee was adjourned to the call of the Chair.)

CHEMICALS IN FOODS AND COSMETICS

TUESDAY, FEBRUARY 19, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE
THE USE OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74, and H. Res. 447, 82d Cong., 1st sess., continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 10 a. m., in room 445, Old House Office Building, Hon. A. L. Miller, presiding.

Present: Representative Miller of Nebraska.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

Dr. MILLER. We will call the meeting to order. The House has a roll call at 12 or shortly thereafter and we will have to adjourn the meeting at that time.

Who is your first witness, Mr. Kleinfeld?

Mr. KLEINFELD. Dr. Harris.

(The oath was administered by the chairman.)

Dr. MILLER. Mr. Kleinfeld, will you proceed with the examination.

TESTIMONY OF ROBERT S. HARRIS, PH. D., NUTRITIONAL BIOCHEMISTRY LABORATORIES, DEPARTMENT OF FOOD TECHNOLOGY, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, CAMBRIDGE, MASS.

Mr. KLEINFELD. What is your academic background, Doctor?

Dr. HARRIS. I have a doctor of philosophy degree from the Massachusetts Institute of Technology. Ever since receiving that degree I have been on the staff of M. I. T., first as research assistant, then as research associate, assistant professor, associate professor, and full professor. I am also director of the nutritional biochemistry laboratories of that institution.

Mr. KLEINFELD. When did you receive your Ph. D. degree?

Dr. HARRIS. In 1935.

Mr. KLEINFELD. And what kind of work did you do in connection with obtaining your degree?

Dr. HARRIS. Well, my doctorate thesis was on the function of chlorophyll compounds in the cure of nutritional anemia.

Mr. KLEINFELD. Since obtaining your degree what has been your special field of professional interest?

Dr. HARRIS. Well, it has been in a variety of directions all in the field of nutritional biochemistry. I have done research in vitamin D, thiamine, riboflavin, calcium metabolism, fat metabolism, studies with radioactive calcium in human subjects, radioactive iron in human sub-

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jects, studies in deuteriumated fatty acids in animals. My name has appeared on about 125 scientific articles during this period.

Mr. KLEINFELD. Have these been published in the professional publications?

Dr. HARRIS. Yes, sir.

Mr. KLEINFELD. Do you belong to any professional societies?

Dr. HARRIS. I belong to the American Institute of Nutrition, the British Nutrition Society, the American Chemical Society, the American Association for the Advancement of Science, the New York Academy of Science, American Public Health Association, and several others.

Mr. KLEINFELD. Do any of the papers you have published deal with dental caries?

Dr. HARRIS. We have published just two papers in this field.

Mr. KLEINFELD. Dr. Harris, will you please read your statement, and speak a little louder, please.

Dr. HARRIS. Mr. Chairman.

Dr. MILLER. Dr. Harris.

Dr. HARRIS. The statement I am about to make expresses my personal views and is not to be construed as representing the attitude of the Massachusetts Institute of Technology which is an educational institution and does not take any position on this matter. The fluoridization of public water supplies is a controversial subject. This controversy is based partly on philosophical grounds and partly on differences in scientific opinion. I have no philosophical interest in this matter. I am interested entirely in the scientific data which indicate that fluorine in water supplies is effective in combating dental caries and in the scientific data which indicate that fluorine is toxic to human beings. Even though many of the studies of the effectiveness of fluorine in water supplies appear to have been designed to demonstrate the good effects of fluorine without evaluating the possible harmful effects of fluorine it is, in my opinion, clearly evident that fluorine is effective in reducing the incidence of dental caries in child populations. It is more effective when the level in water supplies is above 2 parts per million—2 p. p. m. In most areas, however, the level of dosage has been set at about 0.8 to 1.0 parts per million because this level appears low enough to avoid fluorosis and yet high enough to produce measurable protection against tooth decay.

All students of this problem will admit that fluorine is a toxic substance if taken in sufficiently large amount. Thus, the scientific controversy is not involved in the question as to whether or not fluorine in water supplies will effectively reduce dental caries, but rather whether or not the toxic effects of fluorine at about 1 part per million in public water supplies are insignificant. If the good effects of fluoridization greatly outweigh the evil effects, then one may be justified in concluding that fluoridization is a valid public-health procedure, especially if biochemical processes are not measurably affected. If the good effects of fluorides can be obtained without exposing the body to its evil effects, then one is justified in preferring the topical application of fluorine to the teeth rather than the fluoridization of water supplies.

It is clear then that fluoridization is a calculated risk. Certainly it is not possible to calculate this risk until all important factors in the equation are known. It seems to me that an earnest student of

this problem must have the answers to most of the following questions before he is in a position to decide whether the fluoridization of public-water supplies is in the interests of the health of the public.

1. For which species of experimental animal is fluorine the most toxic? Has this species been used in extensive studies of fluorine absorption, metabolism, and excretion?

2. Have the compounds advocated for fluoridization of water supplies been fed during the entire life span of this species, and other species, at levels approximating 25 or 50 times the expected human exposure, as advocated by the United States Food and Drug Administration in testing chemical additives to foods? What were the effects on growth, food utilization, organ weights, reproduction, biochemical functions—especially enzyme functions—and what were the histopathological results?

3. If more were known about the etiology of tooth decay, is it likely that fluorine would be found to be effective for certain types of decay and to be ineffective against other types?

4. Since fluorine reduces the incidence of tooth decay without preventing tooth decay, is this evidence that fluorine is not the answer to the caries problem?

5. Is there not considerable evidence that caries can be produced by a variety of procedures, and considerable evidence that caries can be prevented by many chemical and biochemical agents? Is this proof that fluorine deficiency is not the cause of dental caries in man? Can the effectiveness of fluorine be taken as evidence also that fluorine is a pharmacologic agent, rather than a specific agent?

6. Has any investigator succeeded in producing dental caries in animal or man, using a diet devoid of fluorine but adequate in all nutrients? Has it been proven that fluorine is an indispensable nutrient for animals or man?

7. What compounds are formed when fluorine reacts with enamel? What element does it replace? Is this fluorapatite normal?

8. Is peridontal disease more prevalent than dental caries? What is the effect of fluorine on peridontal structures?

9. If the femur contains 15 times as much fluorine as the tooth—gram for gram—is it scientifically valid to use the tooth as the criterion in evaluating the possible harmfulness of fluorine?

10. Are the methods for the determination of fluorine concentrations in water supplies, and in various body tissues, sufficiently reliable to permit valid conclusions? Do we know how to correlate biochemical and chemical data with toxicological and histopathological data.

11. Have fluoridization studies been conducted long enough to determine effects on growth of the body, growth of bones, opacity of bones, et cetera? Have we a clear picture of the toxicology and pathology of fluorine?

12. Low bacterial counts have been noted in the salivas of subjects receiving fluorinated water. Is this not evidence that 1 part per million of fluorine affects the enzyme systems of bacterial cells? If so, should not the same concentrations of fluorine affect enzyme systems in man?

13. Would it not be more reasonable to evaluate the effects of fluoridization programs using the first molar and to deemphasize data on deciduous teeth?

14. What are the scientific and practical advantages of topical application over fluoridization of water supplies; and vice versa?

15. Is there a variation in the susceptibility of individuals to the benign and to the adverse effects of fluorine? What are the limits of this variation?

16. Is it known whether there are any illnesses which predispose human beings to the toxic effects of fluorine?

17. What are the variations in the water consumption of individuals in the same areas and in different areas according to season, occupation, age, et cetera?

18. Do the several foods in the diet, and the various nutrients in these foods, affect the absorption, metabolism, and excretion of fluorine?

19. Is this the only public-health measure which will not fully protect over 50 percent of the population? Will not the public expect as full protection as it now gets from chlorination, pasteurization, and vaccination?

I have followed closely the literature on fluorine compounds (*a*) because years ago excess fluorine presented a nutrition problem, (*b*) because recently fluorine has been suggested as a nutrient essential, and (*c*) because our research group has long been interested in the role of nutrition in the prevention of tooth decay.

The literature indicates that fluorine at 1 part per million in water supplies can effectively reduce the incidence of caries in children in certain areas. The literature does not indicate, however, that the continued ingestion of fluorine at this level is harmless. The literature does not adequately answer many of the questions listed above. Therefore, it is my opinion that considerably more research on the toxicity of fluorine should be conducted before this interesting means for reducing tooth decay in man is extended. At present I am in favor of the topical application of fluorine. I am not convinced that the safety factor for fluorine has been established for healthy and unhealthy human beings at various ages and therefore feel that I cannot take a position either for or against the fluoridization of public water supplies.

Dr. MILLER. Go ahead with your questions, Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Harris, you say that you have followed closely the literature on fluorine compounds. Does that include following the literature in connection with the fluoridation of public drinking water?

Dr. HARRIS. Yes, it does.

Mr. KLEINFELD. And you say that in your opinion the literature does not adequately answer many of the questions which you have listed in your statement.

Dr. HARRIS. That is right.

Mr. KLEINFELD. And you say also it is your opinion that considerably more research on the toxicity of fluorine should be conducted before this means of reducing dental caries is extended.

Dr. HARRIS. Yes.

Mr. KLEINFELD. Dr. Harris, you know that water containing about 1 part per million or more is found naturally in various parts of the country; is that correct?

Dr. HARRIS. That is true.

Mr. KLEINFELD. Well, those who recommend the fluoridation of drinking water have stated that there is no evidence that people who live in such areas, where we find fluorine occurring naturally in the water, are afflicted any differently or any more frequently by any disease or any physical disorder than those people living in areas of the country where the water does not normally contain any fluorine. Is not that sufficient to establish the safety of adding a fluoride, such as sodium fluoride, to drinking water in the amount of about 1 part per million?

Dr. HARRIS. I don't think that it is. It certainly can be taken as evidence that fluorine is not toxic enough to cause a large number of deaths or a large incidence of certain specific diseases. It is necessary in my opinion to set up a study in which the people in nonfluoride areas are given fluorine in the water supply and to compare the results over a long period of years with those of another group of people receiving the same water supply without fluorine. In that way these effects can be observed.

We must admit that the amount of 1 part per million in fluorine in water supplies is not a very toxic dosage. There is no evidence that that is so. But there is plenty of evidence to indicate that fluorine in this amount or slightly more interferes with enzyme systems, and these enzyme systems are involved in the growth of bones, in the functioning of nerve tissue and so forth, and it is difficult by population surveys to get any precise evidence on this question.

Another procedure would be to set up animal experiments and to feed fluorine over long periods of time and observe carefully in these animals what effects are produced. Then having a clear picture of the kind of effect that might be produced in the animal colony to look in the human population for this type of evidence.

I have indicated in one of my questions that we do not have a clear idea as to what is the toxicology of fluorine, and until we have a clear idea of that we cannot study human populations and say there is no evidence that fluorine in the water of these regions has had no effect.

Mr. KLEINFELD. Then you think it is important that these experimental studies be carried on with animals?

Dr. HARRIS. Yes, I think that this kind of problem must be attacked first in the laboratory.

Mr. KLEINFELD. From your reading of, and familiarity with, the literature, do you know whether such experimental work has been done and the results published anywhere?

Dr. HARRIS. I have seen nothing on that subject.

Mr. KLEINFELD. Are you familiar with the various controlled pilot studies now in progress in various areas of the country, such as the Newburgh-Kingston studies and the ones being conducted at Grand Rapids, Mich., and Evanston, Ill.?

Dr. HARRIS. Yes, I have seen the reports of the results of those studies, and I have talked with several of the investigators.

Mr. KLEINFELD. Are you familiar with the types of medical examinations and the groups upon whom these examinations are made within these pilot cities?

Dr. HARRIS. Yes, in general.

Mr. KLEINFELD. Are you satisfied that these examinations are sufficient to insure that the population as a whole will not be injured by ingesting 1 part per million of fluoride in their drinking water?

Dr. HARRIS. I would say that these studies are very excellently designed to show the beneficial effects of fluorine. I feel that some observations have been omitted from these studies which might have given more information on the adverse effects of fluorine.

For instance, in the Newburgh study they did not examine the children at the beginning to determine the incidence of fluorosis in the teeth. Without these data it is imposible to conclude from this study whether the fluoridization of the water supply produced mottling of the teeth. It is admitted that this mottling is a cosmetic effect, but still people with mottled teeth are not as handsome as people without mottled teeth. And certainly mottling of teeth is evidence of a storage of fluorine in a certain organ of the body.

Mr. KLEINFELD. Do you know whether the people who are conducting the pilot experiments in these cities are examining regularly and periodically people of the older groups of our population?

Dr. HARRIS. To my knowledge the studies are concerned primarily with children.

Mr. KLEINFELD. Do you have any opinion as to whether the studies should include studies of the effects, if any, upon other groups of population, like the aged?

Dr. HARRIS. If the purpose is to fluorinate the water supply of children, then these studies are all right. If the purpose is to show that the incidence of dental caries of children is reduced by fluorine, again, it is all right. But the problem is to know about the effect of fluorine on the rest of the population. Since the intent, apparently, of most people who are interested in fluoridization is to fluoridate all the water supply in a community, then these studies certainly should include investigations of all age groups in the population, with special emphasis, perhaps, on the aged because they might be more susceptible to fluorine than the younger age groups.

Mr. KLEINFELD. Do you think it would be advisable to have studies made of both children and older people who are suffering from some kidney disorders?

Dr. HARRIS. Yes. One of the questions I asked was aimed in that direction. There is some evidence in animals that with certain disorders, especially kidney disorders, fluorine is more toxic than in the normal animal. I think it is important to know whether people with the diseases with which humanity is usually inflicted are more sensitive to fluorine than the people who are healthy. Until we know about that, I think we are on dangerous ground in fluorinating the water supplies.

Mr. KLEINFELD. Dr. Harris, I believe it is normally sodium fluoride which is recommended for the fluoridation of public drinking water. Now, in those areas where the water naturally contains fluorine, do you know whether that fluorine appears in the form of sodium fluoride?

Dr. HARRIS. I never have analyzed water from that point of view. From what I know of chemistry, I am quite sure fluorine occurs in a variety of compounds, some of it in free form or ionized. There may be very small amounts in the form of other salts.

Mr. KLEINFELD. Would it be significant, in your opinion, that the fluorine present naturally in drinking water was in the form of sodium fluoride or some other compound?

Dr. HARRIS. I doubt it. I think that when sodium fluoride is added to the water it goes into solution and you have free fluorine and free sodium to a large extent. If you add it in the form of some other salt, you will have free fluorine and free some other radical. Since fluorine is presumed to be the active part, it would not much matter what form was put into the water. It might matter, of course, as to the toxicity of the various forms. It is not likely that they all have the same toxicity.

Mr. KLEINFELD. Is not that a rather important consideration?

Dr. HARRIS. It might be. It should certainly be considered.

Mr. KLEINFELD. Well, if that is true, Doctor, should not experimental work also be done in that direction?

Dr. HARRIS. Yes. I think I infer in my questions that the work ought to be based on those compounds which are intended to be added to the water supplies. The fluorine that is present in foods, for instance, is very likely not nearly as available for this purpose as the fluorine contained in water, but certainly extensive studies should be done on those compounds that are to be added to public water supplies.

Mr. KLEINFELD. Dr. Harris, in the second question which you pose on the second page of your statement, you say this:

> Have the compounds advocated for fluoridization of water supplies been fed during the entire life span of this species, and other species, at levels approximating 25 or 50 times the expected human exposure as advocated by the United States Food and Drug Administration in testing chemical additives to foods?

Now, these are very high levels; are they not?

Dr. HARRIS. Yes; they are.

Mr. KLEINFELD. Well, what value do we get from using such high levels, if any?

Dr. HARRIS. If, at these levels, there is no toxicity it shows there is a large factor of safety in the use of these compounds. If, on the other hand, there is toxicity, it gives an indication as to what organs and tissues and biochemical processes are affected by the fluorine. You can then pass on to the human species and look for these evidences in human beings.

Mr. KLEINFELD. Do you know whether such experimental work with fluorides at these levels have been carried on with experimental animals?

Dr. HARRIS. I have searched the literature hoping I could find it, and I have not found such a publication.

Mr. KLEINFELD. On page 2 of your statement, question 5, you say that caries can be prevented—as I understand your statement—by a variety of procedures; also, that it can be produced by a variety of procedures.

As I understand your statement, that holds true for procedures other than the fluoridation of drinking water?

Dr. HARRIS. That is right.

Mr. KLEINFELD. Have you done any specific work in this connection?

Dr. HARRIS. Yes. First, I might say we have published the results of some research that is still under way in the Archives of Biochemistry, volume 26, No. 1, page 155, 1950, and in the New England Journal

of Medicine, volume 244, page 361, 1951. We have one or two other papers that have not yet been published.

In these studies we obtained milk and corn from Texas, the area of Texas where there is essentially no tooth decay. We collected corn and milk from New England where there is the highest incidence of tooth decay. These two foods were fed in diets to hamsters over a period of 3 months. At the end of the 3 months the teeth of the hamsters were examined, and it was observed that the hamsters fed the Texas food had 40 percent as much dental caries as those fed the New England food.

We analyzed these diets for fluorine content. We found that there was a difference, but that the amount of fluorine in the Texas diet was too low to have produced any measurable effect on dental caries. This observation had been made by others before.

Thus it appeared that the effects we were observing were not due to fluorine differences.

We conducted studies to find out whether it was the corn or the milk that produced this effect by feeding four diets: New England corn, New England milk; Texas corn, Texas milk; New England corn, Texas milk; and Texas corn, New England milk. At the end of the feeding period we examined the teeth of the animals and we found that the three groups that were fed New England food in the diet all showed about the same degree of dental decay. Only in the case of the group fed the all-Texas diet did we find a reduction in dental decay.

These results indicated that both the corn and the milk were factors in this experiment. These results also indicate, in our opinion, that there was something in the New England foods which caused tooth decay rather than something in the Texas foods that prevented tooth decay.

Since then we have conducted a study with riboflavin. We analyzed these diets for all the nutrients that we had method for and found that the Texas diets were about 30 percent lower in riboflavin than the New England diets. So, we set up an experiment and added riboflavin to the Texas diet. In one case we made the riboflavin value equivalent to the value in the New England diet, and in another case we gave 10 times as much riboflavin. By this experiment we showed that riboflavin was not responsible for causing tooth decay in the New England diet.

In fact, our data showed very definitely that riboflavin is an anti-caries factor.

We have not done the experiment—we intend to—to feed riboflavin in the diet to make comparison with fluorine, but the data so far obtained indicate that riboflavin is about as effective in preventing caries in hamsters as is fluorine. Riboflavin is a vitamin nutrient without any toxicity.

We also have found that the New England foods differ quite a lot from the Texas foods in respect to certain elements. We found three to five times as much manganese and magnesium and copper in the New England corn as in the Texas corn. We are now conducting experiments adding these three elements to the Texas diet to find out if they will induce dental decay.

There is some literature out of Norway indicating that magnesium and manganese are cariogenic.

This type of result indicates that we ought to be careful about some of our conclusions about tooth decay in human populations in the United States.

It has been observed that people in Texas, for instance, have much less tooth decay than people in New England. Then it was observed that fluorine is effective in the prevention of tooth decay. Then it was concluded that the difference in tooth decay in these two population groups is due to differences in fluorine. I admit that may be part of the answer—that there is a difference between these two areas of the United States because of differences in the fluorine content of the food or water supply. But our data indicate that this is not the only answer. In fact, I am not sure that it is the most important answer. Our data indicate that there may be more tooth decay in a human population group because of differences in the composition of food and that this has nothing to do with fluorine. That is one of the reasons why I feel we should be careful in drawing conclusions on the basis of fragmentary evidence.

This subject is very complicated. I can list maybe a dozen different ways to produce dental caries in experimental animals and maybe an equal number of methods of curing dental decay in animals. It is incorrect, I think, and certainly it is not scientific, to try to solve this complicated problem by one device. I think the procedure should be to find the cause of tooth decay in human population and then to remove the cause and thereby remove dental decay.

Dr. MILLER. At that point, you speak about the cause of tooth decay. There may be a number of causes, Doctor, so that you would not pin it down to any one cause perhaps as to tooth decay in children or in adults, and what might cause decay in one youngster might not do it in another?

Dr. HARRIS. That is right.

Dr. MILLER. Is that not true?

Dr. HARRIS. Yes. There are genetic differences that are extremely important.

Dr. MILLER. What is the chemical formula of fluorine and chlorine and bromine?

Dr. HARRIS. Well, it is an element; say, sodium fluoride is NaF.

Dr. MILLER. How is chlorine used in water? Is that a gas?

Dr. HARRIS. Chlorine is added to water as a compound just as fluorine is added as a compound.

Dr. MILLER. What is the relationship between chlorine and fluorine?

Dr. HARRIS. They are two different elements. They are closely alike in many chemical properties, but they are completely different one from the other.

Dr. MILLER. What is the toxic dose of chlorine, for instance?

Dr. HARRIS. I couldn't answer that for you. The toxic dose of chlorine is definitely lower than that of fluorine.

Dr. MILLER. I was going to ask what is the toxic dose of fluorine then?

Dr. HARRIS. That is a question I would like to have answered.

Dr. MILLER. You say we do not know the toxic dose for fluorine; that is, how much water we would have to drink or how much food we would have to eat to get a toxic dose?

Dr. HARRIS. Well, my point is that before you can determine the toxic dose you have to know what symptoms to look for, and that

whole subject has not been explored completely, so that we do not know.

Many people have been willing to rely on fluorosis, a mottling of the teeth, as evidence. If there is no fluorosis, they wish to assume that there is no toxicity.

Dr. MILLER. One might use fluorine in foods of different kinds, and through evaporation and so forth might have rather a toxic dose, then, I presume?

Dr. HARRIS. Well, fluorine occurs in foods, in some foods more than in others.

Dr. MILLER. Of course, there are many things that occur in water. We have some famous springs we go to that have sulfur or iron or something in them, and they smell bad—sulfur dioxide. And I think people mentally think they are getting healthy when they take a little of it, maybe a little laxative effect. Some alkali and various chemicals occur in water naturally in springs and well water.

Dr. HARRIS. That is true. Things that occur in nature are not necessarily nontoxic.

Dr. MILLER. That is right. Now, in the West we have places with so much alkali you can hardly drink the water if you are not used to it because of the laxative effect you get from it. And the same is true of iodine. We know areas in North America where the lack of iodine has some very bad effects upon animals and upon man.

On the use of fluorine, of course, I think we sometimes get off on a sort of mental tangent, thinking, "Well, here is something that is going to prevent decay in teeth," when, as a matter of fact, maybe we have not gone as far as we should in our investigation. I agree with you in some of your questions. There are a lot of questions that have not been answered.

Also you say that you sort of agree that the topical application of fluorine was to be desired. Is not that what you say in your statement?

Dr. HARRIS. I have my own teeth treated with fluorine this way. My point there is that when fluorine is applied topically to the teeth, the dentist—his technique is to dry the tooth surface, then apply a 2-percent sodium fluoride solution——

Dr. MILLER. Two percent?

Dr. HARRIS. Two percent.

Dr. MILLER. That is a pretty good percent.

Dr. HARRIS (continuing). Allow to stand for a few minutes, and then rinse it all off. During that period of time the sodium fluoride has reacted with the surface of the tooth.

Dr. MILLER. Yes.

Dr. HARRIS. And then all the excess is washed away. By this procedure there is no possibility of exposure of the rest of the body to fluorine. The tooth, which is presumed to be the most important thing for treatment here, receives the treatment, but there is no risk of toxicity.

Dr. MILLER. What would be the effect of including a little fluorine in all the food we eat?

Dr. HARRIS. That would be the equivalent of putting it in the water supply. If it is going to be done, I would rather have it in the water supply.

Dr. MILLER. This is really a State problem or municipal problem. If they use fluorine it is going to affect canning, for example, in canning fruit. You would get fluorine in canned fruit.

Dr. HARRIS. Yes.

Dr. MILLER. Through the process of heating and evaporation you might get quite a little fluorine eventually in some of those canned foods.

Dr. HARRIS. That is true.

Dr. MILLER. In areas already having an upper limit of fluorine in their drinking water, what would be the effect of increasing the amount of fluorine, if any? Do you have any data on that?

Dr. HARRIS. Well, where the fluorine content of the water supply is already high, I don't think it would be considered to add more. There are some parts of the world where the problem is just the reverse—they have to treat the water supply to remove fluorine, to bring it down to a level that is not as toxic.

In fact, that is how this whole thing was first discovered. The whole history of this subject was first a public health problem of excess fluoride in certain parts of the country.

Dr. MILLER. Yes. What would be the effect of fluorine on the taste of food in excessive amount? Would it affect the taste of food?

Dr. HARRIS. I am quite sure it would, because it has a flavor, but the amounts in the water supply might be so small that you might not detect it.

Dr. MILLER. Are there any accurate or dependable analytical methods for determination of fluorine under all conditions? Do you know of any?

Dr. HARRIS. Well, fluorine analysis is a very difficult procedure. There are many laboratories that are not in my opinion qualified to do that kind of work. And when you have fluorine occurring in the water supplies or blood samples, and so forth, in animal experimentation, these other materials that occur with it interfere with the analysis.

I have done very little in this direction, but I know that several laboratories exist where an immense amount of fluorine analysis has been made, and the attitude there is it is a very difficult procedure and it is susceptible to variation.

Dr. MILLER. I am wondering about chemicals. Now this committee was out in Washington a few months ago and a small business there was making some kind of an apple jelly and some other processed foods, and they tested the sugar every morning in pears and apples. Every morning it has to be tested to know exactly what tolerance it has and just how much water to put in and how long to soak it and whether to change the formula of making it that day.

Now if we are using fluorine and then some day something happens and they didn't get any fluorine in the water, I suppose that again might change the picture of the pear jelly or the apply jelly. Or would it? I don't know.

Dr. HARRIS. It is possible.

Dr. MILLER. It seems to me rather a delicate balance if they had to test this amount of sugar in these fruits every morning.

Dr. HARRIS. It is quite possible that certain food industries would have to change from the public supply to a private water supply because a problem like that might arise.

Dr. MILLER. Are you a laboratory man, a research man?

Dr. HARRIS. Yes.

Dr. MILLER. Where, if any place, is fluorine stored up in the body after taking it over a period of years, or is it stored up?

Dr. HARRIS. Most of the fluorine is stored in the bones. It is in the hard tissue, the bones and the teeth.

Dr. MILLER. Is there any evidence of it being stored in the liver or in the fatty part of the liver?

Dr. HARRIS. Well, analyses have been made of many organs of the body, and it has been found to be present everywhere, in higher amounts in some organs than others. But it is much higher in the bones.

In one paper I recall it is about 15 times higher in the bones than in the teeth, and higher in the teeth than in other tissues of the body.

Dr. MILLER. Of course, you know, Doctor, the committee is concerned about chemicals in foods. There are several hundred chemicals being used now in foods and fluorine may be one of them. I presume it is. I do not know. What should the attitude of the Pure Food and Drug people be if they find too much fluorine in food in interstate commerce? What would that level be and what would be your suggestion?

Dr. HARRIS. Well, I would advise the Food and Drug Administration to prohibit the addition of fluorine to any food. I don't think food is the proper vehicle for it. I have indicated this morning I don't think there is any proper vehicle for fluorine on the basis of present evidence.

Dr. MILLER. Would you on the same basis say to the Pure Food and Drug people, "You should not permit any chemical to be added to food"?

Dr. HARRIS. No. I testified some time ago before this same committee on this question, and I believe that chemicals should be allowed in foods after the Food and Drug Administration has approved them as being nontoxic in the amounts that are used.

I am heartily in favor of the kind of tests that the Food and Drug has been advocating in the past, and I believe that this kind of test ought to be applied here, because water is food, and any chemical that is added to water should be in the same category as any chemical that is added to foods.

Dr. MILLER. You think the endorsement then by the public health groups, American Dental Association and American Medical Association and similar groups have been premature as to the use of fluorine in water?

Dr. HARRIS. I feel that way; yes. Maybe this comparison is a valid one—I look on fluorine as being like aspirin. If a person has a headache, an aspirin tablet frequently is effective in curing that headache. That does not prove that the headache was caused by aspirin deficiency. The doctor would rather not have the public taking aspirin tablets for their headaches; he would rather find the cause of the headache and then cure the disorder from that cause.

Dr. MILLER. I agree with you. I have felt these services, public health and dental groups and others, were moving a little too fast. It is always easy to whip up a little hysteria that you have got a cure-all here for caries when added to the water, but you get into these things without proper scientific examination of them. I fear maybe that is what is happening in the rush of some of the cities all over the country

to add fluorine to their water without, perhaps, sufficient examination as to what the long-range effect might be. I have the same feeling about some of the chemicals in food.

I think that is all.

Mr. KLEINFELD. Dr. Harris, I have just one or two more questions.

I have a reprint from the Archives of Biochemistry, volume 26, No. 1, March 1950, entitled, "Effect of Foods Growth in Different Areas on the Prevalence of Dental Caries in Hamsters." Is that one of the papers to which you referred?

Dr. HARRIS. That is correct.

Mr. KLEINFELD. I suggest, Dr. Miller, this be made part of the record.

Dr. MILLER. It is so ordered.

(The article referred to is as follows:)

EFFECT OF FOODS GROWN IN DIFFERENT AREAS ON THE PREVALENCE OF DENTAL CARIES AND HAMSTERS

Fluorine in water supplies is considered to be a principal factor accounting for differences in caries prevalence [1] in human subjects in various parts of the United States. The present study is an attempt to determine whether the development of caries in hamsters is affected by diets containing foods grown in areas where there is a high and low incidence of caries.

A modified Hoppert-Webber-Caniff diet [2] of the following composition was used: corn, 63 percent; dried whole-milk powder, 30 percent; alfalfa, 6 percent; sodium chloride, 1 percent. The corn and milk components of diet No. 1 were obtained from Orono, Maine, and St. Albans, Vt., respectively; the soil in both these areas is podzolic. The corn and milk components of diet No. 2 were obtained from Hereford and Lubbock, Tex., respectively, where the soil is red and yellow. The same alfalfa, from Ithaca, N. Y., was used in both diets. These diets and distilled water were supplied ad lib. to hamsters housed in sheet-metal cages resting on wooden flooring. Forty weanling hamsters (19 females, 21 males) were placed on diet No. 1 while 37 (18 females, 19 males) were placed on diet No. 2. Each animal was weighed weekly. After 15, 16, 17, 18, 21, and 23 weeks, representative hamsters (a total of 25 from each group) were autopsied. The heads were fixed in formalin, dried, skinned, and treated with 3-percent hydrogen peroxide. The teeth were examined, scored, and charted for dental caries according to the Keyes procedure.[3] The scoring of caries was spot checked by others with past experience with this technique.

The hamsters gained approximately 5 grams weekly on both diets. Caries were noted in the teeth of hamsters from both groups at the first autopsy, fifteenth week. Male hamsters were more susceptible to caries than female hamsters; maxillary teeth were more carious than mandibular teeth; and there was a very striking preponderance of caries in the occlusal pits of the maxillary molars, par-

TABLE I.—*Incidence and area of caries in hamsters fed diets containing corn and whole-milk powder from New England or Texas during 15 to 23 weeks*

	Diet group		
	No. 1 (N. E.)	No. 2 (Texas)	Difference
Number of hamsters per group:			
Male	13	14	
Female	12	11	
Average number of carious teeth	5.8 (±1.67) [1]	3.4 (±1.83) [1]	2.4 (41 percent).
Average number of carious surfaces	7.4 (±3.19) [1]	3.9 (±2.65) [1]	3.5 (47 percent).
Caries area (square millimeter on score chart).	296.7 (±521.7) [1]	113.7 (±205.5) [1]	183 (62 percent).

[1] Standard deviation.

[1] Nizel, A. E., and Bibby, B. G., J. Am. Dental Assoc. 31, 1619 (1944).
[2] Hoppert, C. A., Webber, P. A., and Caniff, T. L., J. Dental Research 12, 161 (1932).
[3] Keyes, P. H., J. Dental Research 23, 439 (1944).

ticularly the second molars. Only two hamsters (both on the Texas diet) were caries-free.

It will be seen in table I that there was approximately 40 percent more carious teeth, and approximately 50 percent more carious surfaces, in the group fed New England corn and milk. Both these differences were studied statistically and found to be significant at the 1-percent level. It is evident that the area in which foods are grown may affect the prevalence of dental caries. To our knowledge this is the first controlled comparison of the cariogenic effect of the same foodstuffs produced in different soil areas.

Further research will reveal whether the corn, or the milk, or both, were responsible for the differences noted, and investigations are planned to isolate and identify the anticaries or cariogenic factor.

ABRAHAM E. NIZEL,
ROBERT S. HARRIS.

Tufts Dental School, Boston and The Massachusetts Institute of Technology, Cambridge, Mass.

Received December 8, 1949.

Mr. KLEINFELD. I have one other reprint here from the New England Journal of Medicine, volume 244, page 361, March 8, 1951, entitled, "The Caries-Producing Effect of Similar Foods Grown in Different Soil Areas."

Is that also one of the papers to which you referred?

Dr. HARRIS. That is right.

Mr. KLEINFELD. I suggest this also be made part of the record.

Dr. MILLER. Very well.

(The article referred to is as follows:)

THE CARIES-PRODUCING EFFECT OF SIMILAR FOODS GROWN IN DIFFERENT SOIL AREAS [1]

(Abraham E. Nizel, D. M. D.,[2] and Robert S. Harris, Ph. D.[3])

BOSTON

A statistically significant higher incidence of dental caries has been produced in hamsters fed diets containing corn and dried whole milk produced in New England, in comparison to those fed similar foods grown in northwest Texas.[4] The present study was undertaken as a confirmation of these results, and to determine whether the cariogenic factor was in the corn or in the milk, or in both.

Four groups, each containing 35 weanling hamsters, were assembled so that each group had equal distribution in terms of weight, sex, and litter mates. They were fed a modified Hoppert, Webber, and Canniff diet,[5] consisting of corn (ground to 40 mesh fine) 63 percent, dried whole-milk powder 30 percent, alfalfa 6 percent and sodium chloride 1 percent. Distilled water was given ad libitum. The diets varied with respect to the source of the corn and milk as follows:

Group A: New England corn and New England milk
Group B: Texas corn and Texas milk
Group C: New England corn and Texas milk
Group D: Texas corn and New England milk

The animals were housed individually in metal cages with wooden floors and were fed their respective diets ad libitum for a period of 17 weeks. Weekly

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[1] From Tufts College Dental School, Boston, and the Nutritional Biochemistry Laboratories, Massachusetts Institute of Technology, Cambridge.

Aided by a grant from the Charles H. Hood Dairy Foundation. The samples of corn and milk were obtained through the kind offices of the following: Dr. Kenneth C. Beeson, U. S. Plant, Soil and Nutrition Laboratory, USDA, Cornell University, Ithaca, N. Y.; Dr. Arthur C. Fay, H. P. Hood Co., Boston; Dr. B. W. Fairbanks, American Dry Milk Institute, Chicago; Dr. Paul H. Tracy, Department of Food Technology, University of Illinois; Dr. J. J. Willingham, Department of Dairy Manufacturers, Texas Technical College; and Mr. Roy L. Donahue, USDA Extensionist, College Station, Texas.

[2] Visiting Instructor in Clinical Dentistry, Tufts College Dental School.

[3] Professor of Nutritional Biochemistry, Massachusetts Institute of Technology.

[4] Nizel, A. E., and Harris, R. S. Effect of foods grown in different areas on prevalence of dental caries in hamsters. Arch. Biochem. 26: 155–157, 1950.

[5] Hoppert, C. A., Webber, P. A., and Canniff, T. L. Production of dental caries in rats fed adequate diet. J. Dent. Research 12: 161–173, 1932.

weight records showed that all four groups grew well and at the same rate during this period.

At the end of the test period the hamsters were killed and the heads fixed in a 10-percent solution of formalin and then dried and skinned; finally the maxillas and mandibles were treated with a 3-percent solution of hydrogen peroxide. To eliminate bias, the heads were boxed and marked by a code unknown to the dental examiner. The dental caries were scored according to the Keyes procedure.[6]

TABLE 1.—*Comparative caries score of hamsters fed diets containing corn and whole dried milk produced in New England (group A) or in Texas (group B)*

	Group A (New England)	Group B (Texas)	Difference in mean	T value or critical ratio	Difference
Number of hamsters per group:					*Percent*
Male	14	11			
Female	15	17			
Mean number of carious molars	4.52	2.57	1.95	[1] 3.604	43.1
Standard deviation	±2.37	±1.57			
Standard error	±0.448	±0.302			
Mean number of carious surfaces	5.83	2.86	2.97	[1] 3.246	50.9
Standard deviation	±4.29	±2.20			
Standard error	±0.811	±0.423			
Mean size of area of carious molars	340	102	238	[2] 2.016	70.0
Standard deviation	±551	±289			
Standard error	±104	±56			

[1] Statistically significant to 1-percent level.
[2] Statistically significant to 5-percent level.

Table 1 reports the results of the dental caries examination of groups A and B. The 43.1 percent decrease of carious molars and the 50.9 percent decrease in carious surfaces in Texas-fed hamsters over the New England-fed hamsters compared very closely to the initial findings [4] of 41 percent less carious molars and 47 percent less carious surfaces in the Texas-fed group. This duplication of results gives support to the idea that the cariogenic effect of these foods is related to the area where they were produced.[7 8]

TABLE 2.—*Comparative caries score of hamsters fed diets containing New England corn and Texas milk (group C) and Texas corn and New England milk (group D)*

	Group C: New England corn, Texas milk	Group D: Texas corn, New England milk	Difference in mean	T value or critical ratio	Difference
Number of hamsters per group:					*Percent*
Male	17	13			
Female	16	15			
Mean number of carious molars	5.00	4.68	0.32	0.660	6.4
Standard deviation	±1.67	±2.00			
Standard error	±.295	±.385			
Mean number of carious surfaces	6.03	5.86	.17	.197	2.8
Standard deviation	±2.92	±3.61			
Standard error	±5.16	±.694			
Mean size of area of carious molars	270	371	101	1	27.2
Standard deviation	±402	±747			
Standard error	±71	±144			

It may be suggested that these results are due to differences in fluorine. The fluorine content [9] of the milks from Texas and New England was found to be 2.9 and 0.3 parts per million respectively, and of the corns, 0.4 and 0.3 parts per

[6] Keyes, P. H. A method of recording and scoring gross carious lesions in molar teeth of Syrian hamsters. J. Dent. Research 23 : 439–445, 1944.
[7] Nizel, A. E., and Bibby, B. G. Geographic variation of caries prevalence in soldiers. J. Am. Dent. A. 31 : 1619–1626, 1944.
[8] Albrecht, W. A. Our teeth and our soils. Ann. Dent. 6 : 199–213, 1947.
[9] Hodges, H. C. Personal communication.

million, respectively. The fluorine contributed by the corn and milk to diet B is calculated to be 1.3 parts per million, and that contributed to diet A is calculated to be 0.3 part per million. It is not likely that the fluorine contained in diet B was in itself sufficient to produce this difference, for McClure [10] reported that rats and hamsters required at least 10 parts per minute fluorine in the diet for caries inhibition.

Diets A and B were analyzed for 13 nutrients, and only the riboflavin was found to be significantly different; it was approximately 30 percent higher in diet A.

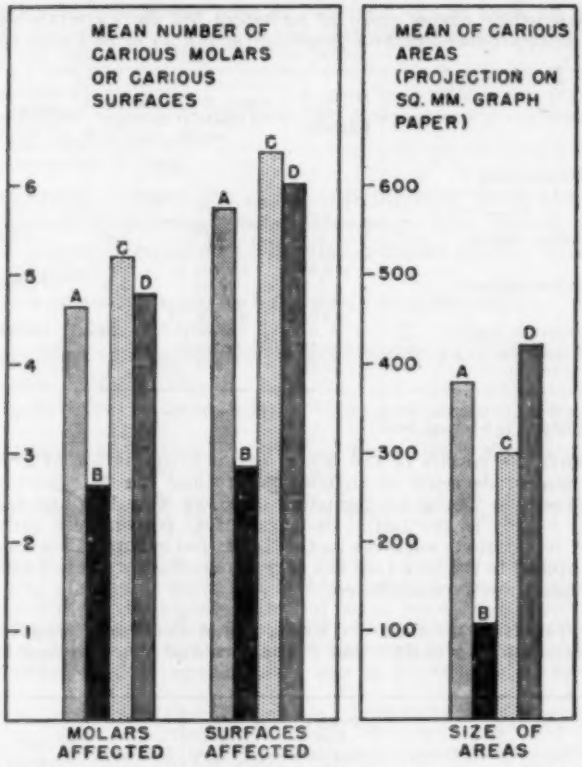

FIGURE 1.—Comparative caries experience of hamsters. (A) New England corn and New England milk, (B) Texas corn and Texas milk, (C) New England corn and Texas milk, and (D) Texas corn and New England milk in diets.

Table 2 presents the dental-caries scores of groups C (New England corn and Texas milk) and D (Texas corn and New England milk). There was no statistically significant difference in the caries index. This indicates that neither the Texas corn alone nor the Texas milk alone inhibited the dental caries.

The relation of all four groups to each other is shown in figure 1. Groups A, C, and D all exhibited a similar prevalence of dental caries, while group B (fed both Texas corn and Texas milk) had a statistically lower caries score than the other three groups.

It appears from these results that the caries-promoting property of the New England foods outweighed any caries-inhibitory property of the Texas corn and milk, and that a mechanism operated in the New England foods that aided materially in production of dental decay. Investigations to determine whether this factor is organic or inorganic are contemplated.

Mr. KLEINFELD. I have no further questions.

Dr. MILLER. Thank you very much, Doctor, for coming before the committee again.

[10] McClure, F. J. Personal communication.

Dr. HARRIS. Thank you.
Mr. KLEINFELD. Is Dr. Taylor here?
(The oath was administered by the chairman.)
Dr. MILLER. You may proceed, Mr. Kleinfeld.

TESTIMONY OF ALFRED TAYLOR, PH. D., BIOCHEMICAL INSTITUTE OF THE UNIVERSITY OF TEXAS, AUSTIN, TEX.

Mr. KLEINFELD. What is your academic background, Doctor?
Dr. TAYLOR. I have a doctor of philosophy degree.
Mr. KLEINFELD. Where did you get your doctor of philosophy degree?
Dr. TAYLOR. Oregon State College.
Mr. KLEINFELD. And what was the work done in connection with your thesis?
Dr. TAYLOR. My particular problem was the effect of thyroidectomy on the salamander.
Dr. MILLER. On what, Doctor?
Dr. TAYLOR. On the salamander.
Dr. MILLER. Amphibious. How many thyroids does a salamander have?
Dr. TAYLOR. They have thyroids very much like ours, one on each side of their neck.
Mr. KLEINFELD. What is your special field of professional interest?
Dr. TAYLOR. At the present time and for the past 11 years, I have been with the Biochemical Institute of the University of Texas, and part of an organization which has been doing extensive work in the field of cancer research. We have also done some work in the field of nutrition.
Mr. KLEINFELD. And you are connected in what capacity with the University of Texas?
Dr. TAYLOR. Research scientist.
Mr. KLEINFELD. How long have you been engaged in that capacity?
Dr. TAYLOR. Eleven years.
Mr. KLEINFELD. Are you connected with the Clayton Foundation for Research, of Austin, Tex.?
Dr. TAYLOR. The Clayton Foundation has been very generous in contributing funds for our work over the entire period.
Mr. KLEINFELD. Are you a member of any professional societies, sir?
Dr. TAYLOR. I am a member of the American Society of Cancer Research, Inc., Society for Experimental Biology and Medicine, a fellow of the American Association for Advancement of Science, and a fellow of the New York Academy of Science.
Mr. KLEINFELD. Have you had any papers published in the professional publications?
Dr. TAYLOR. I have had 53 papers to date, all of which represent scientific reports, published in the journals.
Mr. KLEINFELD. All published?
Dr. TAYLOR. All published.
Mr. KLEINFELD. Generally in what field, sir?
Dr. TAYLOR. Generally in the field of cancer.

Mr. KLEINFELD. Any in the field of nutrition and endocrinology?

Dr. TAYLOR. Some in the field of endocrinology and some in nutrition.

Mr. KLEINFELD. Have you had any papers published in connection with the fluoridation of public drinking water?

Dr. TAYLOR. None.

Mr. KLEINFELD. Are you working on any which may be published?

Dr. TAYLOR. Yes, we do contemplate several papers in the course of time, one of which is now ready for publication.

Mr. KLEINFELD. Please read your statement, Doctor.

Dr. TAYLOR. Mr. Chairman, I appreciate very much the unique importance of the work of this committee to the American people and it is a privilege to be invited to contribute to these open hearings on the fluoridation of public drinking waters.

SODIUM FLUORIDE IN THE DRINKING WATER OF MICE

About 2 years ago experiments were set up in our laboratory to test the effect of sodium fluoride in the drinking water of mice on mammary cancer incidence. The research was undertaken as a part of our continuing project of screening various compounds for possible anticancer effects. The research was not initiated with any thought of possible implications for the current program of fluoridating urban water supplies.

Sodium fluoride in low concentrations is known to inhibit tissue glycolysis (Lipmann, F. Biochem. Ztschr., 227, 110 (1930)) and it has been reported that tumor tissue is more sensitive in this respect than nontumor tissue (Sellei, G., and Jany, J. Biochem. Ztschr., 239, 94 (1931)). Further, experiments have indicated that the respiration of tumor tissue is increased by sodium fluoride whereas nontumor tissue is little affected (Sellei, G. and Jany, J. Biochem. Ztschr., 239, 94 (1931)). Because of such properties sodium fluoride has been investigated by several workers from the standpoint of its possible value in tumor therapy with negative results.

Experiments 1 and 2, tables 1 and 2, were completed before the other experiments were begun. The number, age, and strain of the mice and duration of the experiments are contained in the tables.

The first experiment consisted of C3H mice, a strain in which the females normally die with mammary cancer, that is, naturally occurring tumors account for about 95 percent of deaths in this group.

Each group was maintained as far as possible under identical conditions except that the controls received distilled drinking water and the experimental animals drank distilled water containing 1 milligram of sodium fluoride per liter, which is 0.45 parts per million fluorine, for experiment 1 and 10 milligrams per liter, which is 4.5 parts per million of fluorine, for experiment 2.

We arrived at these levels by experiment. We had just a very slight knowledge of the whole fluoridation program at the time these experiments were begun about 2 years ago, and we simply tried various levels on the mice. We wanted a subtoxic level and we wanted to find the effect of giving this water to the mice over their entire lifetime. By trying various levels we finally arrived at these, which happened to be very close to those that are advocated for public drinking waters. All but three of the deaths recorded for experiment 1 were due to

mammary tumors and all the deaths in experiment 2 were in this category.

The deaths as they occurred are expressed in cumulative percent in table 1. In table 2 the results are shown on the basis of the death rate per 100 animals for each month of the experiment. At the beginning of each month, the control and experimental animals remaining constituted a new group and the death rate for the month was calculated in relation to that number.

Dr. MILLER. Were these experiments all carried out on mice who were susceptible to tumors?

Dr. TAYLOR. Yes. In experiment 1, the mice were 4 months of age, and in experiment 2 they were 6 months of age. A 4-month-old mouse is about like a 20-year-old person. In other words, these were young mice and had this fluoridated drinking water during their youth and middle age. In effect, in these two experiments running a total of 19 months, each month constituted a separate trial. Since there were no deaths in either group for 7 of the 19 months, there remain 12 months when there were deaths in one or both of the distilled and fluoridated water groups. Inspection of these figures in table 2 shows that the death rate was higher in the mice receiving the fluoridated water in every one of the 12 months in which deaths occurred.

Having completed those two experiments, we, of course, were quite impressed. We had not achieved what we had expected, as what we were hoping for was to find something that would lower the incidence of cancer. On the other hand, we had what might be important information. Actually, as our further work showed, there was no change in the incidence of cancer, but the evidence indicated that this condition developed earlier in those receiving the fluoridated water.

Five more experiments have been completed utilizing older female mice already at the age when tumors can be expected. I might interpolate here that the reason we used older mice in these other experiments is that contrary to what we wanted, a rumor got out about this earlier work. We were subjected to quite a little harassment and communication and we were more or less pushed into trying to get something faster. So we used older mice groups in these other five experiments. We did not really want to do that because, as you notice, there is quite a difference between those first two groups and their ages and the rest of the mice in the table.

These other 5 experiments were set up bringing the total number of animals used in these experiments to 141 controls and 140 experimentals, with a total of 281 mice in the 7 experiments. The experimental groups in these 5 experiments all received 2.21 milligram sodium fluoride per liter, which is 1 part per million of fluorine, in the drinking water. Otherwise the procedure was the same as for experiments 1 and 2.

Experiments 3 and 4, as you will observe in the table, utilized a different strain of mice. Experiment 3 consists of 26 in the controls and 26 in the experimental, dba mice, which have about 50 percent incidence of cancer. In the first two experiments we used a high cancer strain, and the second variety of mice had a medium susceptibility.

The total death rate given in cumulative percent and the death rate per hundred per month was higher in the fluoridated water group to about the same degree as in experiments 1 and 2. The death rate per

month shows there were 4 months where the controls were higher and 11 where the experimentals were higher.

In these particular groups, experiments 3 and 4, about half the deaths were noncancer, and that rules out any specific connection with cancer, at least on the basis of these data.

In experiments 5, 6, and 7, C3H female mice were used. The number and age of animals and duration of experiments are shown in the tables. It will be noted that in experiment 5 the controls showed a higher death rate in cumulative percent than the experimental animals. In the 7 months of experiment 5, the death rate per 100 as between the two groups was the same for 1 month and was higher in the experimental animals for 3 of the remaining 6 months. Experiments 6 and 7 showed a higher death rate in cumulative percent in the experimental groups. The death rate per 100 was higher for the fluoridated water group in 11 of the 16 months of these two experiments when deaths occurred in one or both groups, it was the same for 1 month, and higher in the control in 4 months.

As the data indicate, there were for the seven exeperiments 50 monthly records when deaths occurred in one or the other of the paired groups of mice. Of this number the death rate per 100 was the same for both control and experimental groups in two of the months; it was higher in the controls in 11, and higher in the mice receiving fluoridated water in 37.

The results show no change in the incidence of cancer, but rather indicate a shorter life span in the mice receiving the fluoridated water. In other words, if a mouse were destined to die of cancer, this disease developed earlier in the group receiving the treated water, and the same was true for other diseases. It is also noteworthy, that the control and experimental animals appeared to be equal in health and vigor in the predisease state.

The life span of a mouse is about 2 years so that 1 month of a mouse's life is roughly the same as 2½ years of a human life. Experiments equivalent in time to those recorded here if done with human beings would require 17 to 27 years.

It should be emphasized that this study utilized sodium fluoridated distilled water. It cannot be assumed without research that other inorganic fluorine-containing compounds are equivalent from the standpoint of total biological effects. It is also evident that where fluorine occurs naturally in water in unknown complexes a still different problem is presented. The effects of fluoridation may be quite different for hard and soft waters.

In research of this kind many investigations are necessary before one comes to a definite conclusion. It does seem, however, that the weight of the data makes the thesis, that sodium fluoridated water has no harmful effects on the body, open to question and in need of further study.

At the present time other investigations of the biological effects of sodium fluoridated drinking water are in progress in our laboratory. These studies are not yet advanced enough to warrant consideration of particular data. However, it is worth noting that researches into different aspects of the problem have given further indication that drinking fluoridated water—one part per million fluorine—is associated with adverse physiological reactions.

The author is grateful to Dr. Roger J. Williams for his interest and helpful suggestions and to Oleta A. Klatt, Nell Carmichael, and Tamara Sorokin for their collaboration in the research.

The fluoridation of public waters:

At the present time the fluoridation of public water supplies is being vigorously and successfully promoted as a means of improving dental health. The idea is very attractive. It seems to be a simple and inexpensive way to lower the incidence of dental caries for large numbers of people.

Unfortunately, the procedure involves the treatment of drinking water with a low concentration of a highly toxic chemical compound. Since this is so, it is obvious that no one would advocate such a program even though there were gains in dental health if there were any possibility of unfavorable effects on the body. A mistake in an affair of this kind could have very serious consequences, since such a large number of people would be affected. Hence, it would be assumed that the final decision would be made only after careful and exhaustive laboratory research had shown the procedure to be safe for all the people, regardless of age, state of health, or peculiarities of individual biochemistry. However, a search through the literature reveals that the possible nondental aspects of fluoridated water have received very little attention. Further, certain points which may be of critical importance seem to have been completely ignored.

The case for the fluoridation of public waters should be supported by two separate categories of research data, one demonstrating its value in dental health, and the other establishing the absence of unfavorable effects on the body as a whole. It appears that there has been a very great preoccupation with the first of these problems. As a result, the impression is created that only dental tissues are involved and that a fluorine concentration which does not injure the teeth can on that basis alone be considered nontoxic. Also, on the sole criterion of the effect on the teeth, it is assumed that equal concentrations of fluorine have equal biological effects regardless of whether it occurs naturally in the water or is added in the form of various fluorides. In other words, we are not to anticipate that the effect of fluorine on nondental tissues will be influenced by the presence or absence of various other chemical elements or by the type of combination between fluorine and other elements. The real truth about this can only come from laboratory investigation. Nevertheless, the fluoridation program was initiated without research data on this important point.

Another assumption implicit in the program of fluoridating public waters is that people are so biologically and biochemically alike from one individual to another that it is practical to give all the same dosage of a biologically highly reactive chemical. It is admitted that 1.5 parts per million of fluorine has observable toxic effects for many individuals, but those who advocate fluoridation consider that 1 part per million is perfectly safe for everyone. A recent University of Texas publication by Dr. Roger J. Williams and his coworkers contains the report of a laboratory investigation which indicates that human beings differ very much in their biochemistry. Corresponding values obtained from different individuals may vary by as much as several hundred percent.

It is well known, of course, that people differ strikingly in their toleration of various drugs and that individual idosyncrasies must be

considered not only with respect to drugs but even where foods are concerned. It would be surprising if there were not a few people in every thousand with a particular sensitivity to fluoridated water. If such individuals are present in cities that have initiated the program, there is no way of knowing anything about it. In the first place, there can be no dental effects for the great majority of the people; and, since the possibility of nondental effects is denied, it would be impossible for anyone to prove that their illness or lowered vitality was in any way connected with the treated water.

The possible effect of drinking sodium-fluoridated water over most of the life span cannot be known at present, since the first such project was undertaken only about 7 years ago. In the mice experiments there was no observable difference in health between mice drinking the treated and the untreated water in the predisease stage. It has been reported that 90 percent of the fluorine taken into the system in the form of sodium fluoride is excreted through the skin and kidneys. This still leaves the possibility of a considerable accumulation of fluorine in the period from birth to middle and old age. Also, these tests were undertaken with young men near the peak of their biological effectiveness. What would be the effect on old people or on individuals suffering from various chronic illnesses?

There is one minor point that seems worth some comment. The sponsors of fluoridation state that it is analogous to chlorination, but there is a vital distinction. Chlorine is put into the water as a gas to purify it. As the water comes from the tap some of this gas is dissipated, and slight heating drives off that which remains. Fluorine is put into the water as a fluoride, which remains permanently for the purpose of affecting a body tissue, the teeth. In other words, fluoridation is very definitely a type of medication, whereas chlorination is just as definitely not.

Those who have endorsed the fluoridated-water program are free from all doubts concerning any possible ill effects such treated water might have on the human body. It is unthinkable that where so much is at stake they would advocate such a measure if they considered there was the slightest basis for uncertainty. Hence, it follows that to them research on this aspect of the program is unnecessary since it must, if it is a valid investigation, merely confirm what they already know.

It is a little difficult to understand how this state of complete assurance about the matter has arisen and in so short a time. In an article entitled "Epidemiological Studies in the United States," by Dr. H. Trendley Dean, Dental Director, United States Public Health Service, presented in 1944 and appearing in a publication of the American Association for the Advancement of Science entitled "Dental Caries and Fluorine," there appears this statement:

> Assuming that properly planned and sufficiently complete studies demonstrate the harmlessness of long-continued use of waters of considerably higher fluoride concentration than 1 part per million for effects other than the teeth, it would seem that the next step would be a practical test of his hypothesis, utilizing human populations.

Just 1 year later, 1945, the fluoridation of a public water supply was instituted in Grand Rapids, Mich., and in several other cities.

It would seem that public interest would be best served by a more cautious attitude before instituting a program which involves adding a

chemical to drinking water that is so toxic it has been used for years as a rat and roach poison. No matter how low the concentration of such a toxic compound in the drinking water may be, the public should have the benefit of the doubt and the procedure should be considered harmful until proved otherwise.

(The charts presented by Dr. Taylor are as follows:)

TABLE 1.—*Total deaths in cumulative percent for female mice supplied fluoridated (experimental) and distilled (control) drinking water*

	Experiment 1 C_3H		Experiment 2 C_3H		Experiment 3 dba		Experiment 4 dba		Experiment 5 C_3H		Experiment 6 C_3H		Experiment 7 C_3H	
	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental
Number of mice	21	20	13	13	26	26	19	20	19	18	18	19	25	24
Average initial age (months)	4	4	6	6	13	13	10	10	9	9	9	9	9	9
Month of experiment.														
1	0	0	0	0	8	19	11	5	5	6	0	5	4	13
2	0	0	0	0	19	38	16	25	26	6	0	5	20	17
3	0	0	0	0	27	42	21	55	37	28	17	37	28	25
4	0	0	0	15	31	50	37	70	42	33	50	58	36	29
5	10	15	15	31	50	65	68	80	63	44	56	63	36	46
6	10	25	23	54	54	73	68	80	68	44	72	89	48	58
7	19	40	31	62	69	81	68	85	79	67	89	100	56	71
8	38	60	38	69	77	89	.....	.....	.....	.....	.....	.....	68	71
9	67	70	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	72	83
10	71	75	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	76	88
11	76	80	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....

TABLE 2.—*Death rate per 100 mice per month for female mice supplied fluoridated (experimental) and distilled (control) drinking water*

	Experiment 1 C_3H		Experiment 2 C_3H		Experiment 3 dba		Experiment 4 dba		Experiment 5 C_3H		Experiment 6 C_3H		Experiment 7 C_3H	
	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental	Control	Experimental
Number of mice	21	20	13	13	26	26	19	20	19	18	18	19	25	24
Average initial age (months)	4	4	6	6	13	13	10	10	9	9	9	9	9	9
Month of experiment:														
1	0	0	0	0	8	20	10	5	5	6	0	5	4	12
2	0	0	0	0	12	24	6	22	23	0	0	0	17	5
3	0	0	0	0	10	6	6	43	14	24	17	33	10	10
4	0	0	0	15	5	14	20	30	8	8	40	33	11	6
5	10	15	15	18	28	30	50	28	36	17	9	12	0	24
6	0	12	8	33	8	20	0	45	14	0	37	71	19	23
7	5	18	10	17	34	28	0	20	33	40	60	100	15	29
8	29	33	11	20	25	40	.....	.....	.....	.....	.....	.....	27	0
9	23	25	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	13	43
10	14	20	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	14	25
11	17	25	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
Avg	9	13	6	13	16	23	13	28	19	14	23	36	13	18

Dr. MILLER. Let me ask the doctor a question.

Does fluorine form a chemical reaction with other chemicals? Say you had fluorine with other chemicals, whether alkali or acid, would you get some other chemical, or a chemical reaction?

Dr. TAYLOR. Very likely. There has not been much work done as far as conditions in water supply are concerned, but——

Dr. MILLER. Would fluorine unite with calcium or calcium fluoride?

Dr. TAYLOR. There are various forms of fluorides.

Dr. MILLER. What do you get, for instance, with calcium fluoride and fluorine mixed together?

Dr. TAYLOR. Calcium fluoride is a relatively stable compound, and there should be no effect.

Dr. MILLER. The magnesium in Epsom salts, what reaction would you get from mixing it with fluoride?

Dr. TAYLOR. There would probably be some reaction between the two.

Dr. MILLER. Do you know of any toxic chemical that might be formed when fluorides might be mixed with something that would be more or less nontoxic?

Dr. TAYLOR. I do not have any information on that.

Dr. MILLER. You say sodium fluoride is used in rat poison?

Dr. TAYLOR. Sodium fluoride has been used for many years as rat poison. In fact, one of the manufacturers told me that was the chief use of it until recently.

Dr. MILLER. Does it taste good, or has anybody tried to taste it; do you know? The rats apparently like it.

Dr. TAYLOR. Apparently it must be fairly tasteless because rats are pretty discriminating animals.

Dr. MILLER. In what form is it used—in a biscuit, and what concentration?

Dr. TAYLOR. I don't know. I never happened to use it as rat poison. In roach poison, sodium fluoride is used as a powder.

Dr. MILLER. Now, when you put sodium fluoride in the water, or whatever they use in the water to fluoridate, is that dissolved, like chlorine?

Dr. TAYLOR. It is dissolved as a fluoride. To chlorinate the water, chlorine gas is used; but to fluoridate, the element is added in the form of a salt like putting sodium fluoride in the water.

Dr. MILLER. Is it as easy to control as chlorine when you use chlorine gas? Are the fluorides as easy to control as the chlorine?

Dr. TAYLOR. I do not know too much about it; but, from what I know, it does seem to be as easy to handle it from that standpoint.

Dr. MILLER. Speaking about the fluorides in water, of course, we use water for some of the things like canning fruits, in tea and coffee and beer and wine and a lot of places. Would the use of water that has fluorides in it affect beer or wine or canned fruits?

Dr. TAYLOR. I have not encountered any reports in this regard.

Dr. MILLER. I was out in a section of the country this last week where they advertise a beer that is made out of spring water, and something happened to the spring water. They had to go to some other water, and there was something in the water that affected this beer. They had to get back to the spring water in order to get the best type of beer that people liked. I am wondering whether the

fluorides that might come into this or wine or even in the making of preserved fruits might affect it.

Dr. TAYLOR. It might affect the yeast, of course. I do not know.

Dr. MILLER. Would you say what would happen with the hops and yeast? Would there be a chemical reaction of some kind that might change the formula or the taste of it? Is not that possible?

Dr. TAYLOR. Very possible. We do know, of course, in the mouth certain bacteria are affected.

Dr. MILLER. When you boil water are the fluorides boiled out?

Dr. TAYLOR. No.

Dr. MILLER. No?

Dr. TAYLOR. No; you can boil it down to the residue and still have the fluorides.

Dr. MILLER. If I take a gallon of water and am going to make some preserves out of it and mix whatever I am going to put in there to make preserves, and I boil the water, it might be that I get a little heavier dose of fluorides in this preserved article because I eliminate the water?

Dr. TAYLOR. Absolutely. Or if a woman leaves a kettle on and boils it down, as they do, and get absent-minded while making a cup of tea, she might have 10 times the amount of fluoride she would have normally.

Dr. MILLER. I was going to come to that next. It cannot boil down?

Dr. TAYLOR. No.

Dr. MILLER. It is not like chlorine?

Dr. TAYLOR. The chlorine goes out.

Dr. MILLER. It disappears?

Dr. TAYLOR. Yes.

Dr. MILLER. Some of the bromides disappear in the atmosphere.

Dr. TAYLOR. That is right.

Dr. MILLER. So, if I took a large amount of water and boiled it down trying to get distilled water, I would still have some fluorides?

Dr. TAYLOR. That is right.

Dr. MILLER. Something in the water that would not be good for us?

Dr. TAYLOR. That is right. The more the water is boiled the higher becomes the fluoride concentration.

Dr. MILLER. I wonder, too, in surgical operations where they use the water to boil instruments, whether it has any effect on nickel or the instruments sometimes used. I suppose it is too small an amount, unless you had large amounts of fluoride.

Dr. TAYLOR. Probably so.

Dr. MILLER. I think you would get some reaction eventually if you used too much fluoride in some of the water.

What cities now presently use fluorine in their water; do you know?

Dr. TAYLOR. I do not know. Of course, that is really out of our field, you see.

Dr. MILLER. I know, you are scientists. Do you think this Congress or this committee—of course we are not a legislative committee, but we are going to make some recommendations, I guess, after a while—do you think that Congress itself ought to pass some law regulating fluorine in water, or should we leave it to the several States and cities to make that decision?

Dr. TAYLOR. I think if they have all the facts, that the people can be depended upon to decide this very effectively.

Dr. MILLER. If we give them all the facts?

Dr. TAYLOR. We have had a lot of correspondence, and just on the little bit we have done a number of cities—in fact, 20 cities in Texas are holding off the program because of the work we are doing in the laboratory, even though these cities are subjected to a lot of pressure from other sources trying to get them to hurry up with the program.

Dr. MILLER. It is well this group interested themselves in this particular subject as to what would happen with the use of fluorides.

As a doctor, it seems to me people are a little bit anxious about it and may be going into the program without knowing exactly what might happen.

Dr. TAYLOR. We have letters—people ask us if sodium fluoride is toxic—showing how little information there is in many quarters.

Dr. MILLER. For instance, in rat poison it might be toxic?

Dr. TAYLOR. Yes.

Dr. MILLER. If you told people you put rat poison in water to cure caries, it might raise several eyebrows.

Dr. TAYLOR. Yes.

Dr. MILLER. I do not think you ought to say that, though, and the press maybe ought to tone that down a little.

Dr. TAYLOR. After all, it is a fact, and about the only way you can bring home the fact.

From the standpoint of physiology, we consider sodium fluoride to be one of the most biologically active compounds. We use it in all sorts of vitro experiments. I have quite a lot of respect for the toxicity of this compound, and I think we might as well know the facts about it.

Dr. MILLER. That is true also of other chemicals we take in food if we take an overdose—it is poisonous.

Dr. TAYLOR. I know of no other chemical used in food or drink which is toxic enough to be used as a practical poison.

Dr. MILLER. Yes.

Dr. TAYLOR. The fact that it was used as a rat poison shows it has a high order of toxicity. There are only a few compounds you can use in that way.

Dr. MILLER. Of course, it is rather difficult to get around testimony like we had earlier before the committee. Dr. Bruce D. Forsyth, Assistant Surgeon General, Chief Dental Officer, Public Health Service, appeared before the committee on February 13 this year, and in his closing statement I notice he said this:

> Again in my opinion it is the most remarkable public-health preventive developed in this country. It is not a question—can a community afford fluoridation of drinking water, but can a community not afford fluoridation.

Dr. TAYLOR. From the standpoint of research we think there is a doubt. That is all I am trying to say. I do not say I know it has bad effects, but I think the weight of our research is such that there should be a doubt.

Dr. MILLER. Do you know whether the American Public Health Association or the Association of State and Territorial Health Officers or the National Research Council and the American Medical Association carried on any research before they endorsed it?

Dr. TAYLOR. We have been trying to find some record of research done with animals on this problem, as I pointed out and as the gen-

tleman before me pointed out, and we have not been able to find any record of such research.

Dr. MILLER. I think that is all.

Mr. KLEINFELD. Dr. Taylor, in connection with your experiments which you described in your statement, with the exception of the drinking water were the controls and experimental mice in the same experiments fed exactly the same diet?

Dr. TAYLOR. They were fed the same diet. We used Purina, a laboratory chow used by a great number of laboratories all over the country, and we have used it for about 10 years. This diet has fluorine in the fish meal that it contains.

Mr. KLEINFELD. How much fluorine?

Dr. TAYLOR. Pardon me.

Mr. KLEINFELD. How much fluorine?

Dr. TAYLOR. We have never made any analysis ourselves. The only analysis we have was one made here in Washington, and in that particular sample it ran around 38 parts per million.

Mr. KLEINFELD. That is a pretty considerable amount, is it not?

Dr. TAYLOR. That is, but, of course, if the fluorine was in the form of some insoluble compound it would not necessarily have any biological effects. There is quite a difference between taking fluoride in food and in water. The water immediately gets into the blood and throughout all the tissues. In the food the element ordinarily will go through the liver, and the liver is a detoxifier.

We have been giving our mice this diet for about 10 years. The experimental and control groups of mice consisted of paired cages of inbred animals, both groups receiving this diet. The only difference then was the sodium fluoride in the drinking water of the mice in the experimental group. It has not been shown that fluorine in the food was present in the form of sodium fluoride which was the compound we used in the drinking water.

Mr. KLEINFELD. Why did you use that particular diet which consists of a fairly large amount of fluoride?

Dr. TAYLOR. It is a standard diet.

We are doing experiments now in which the mouse diet contains practically no fluorine, and we have had the same results so far. So that we are not very concerned. We are not claiming these data are infallible, and all we say is that they insinuate a doubt, certainly pointing to the necessity for more research.

Mr. KLEINFELD. The same as what?

Dr. TAYLOR. Sodium fluoride in the drinking water is associated with bad physiological effects.

Mr. KLEINFELD. What diet are you using in those experiments?

Dr. TAYLOR. Whole grain, powdered milk, and various other ingredients, for instance, barley, wheat, rolled oats, and so on. A very good diet which does not contain an appreciable amount of fluorine.

Mr. KLEINFELD. Have you completed those experiments yet?

Dr. TAYLOR. No. The type of experiment, however, is such we hope within a few months to be able to have a report.

Mr. KLEINFELD. Would you say you have any——

Dr. TAYLOR. So far they substantiate these first results.

Mr. KLEINFELD. And you say a number of cities in Texas are holding up fluoridation of their drinking water because of the experimental work you have carried on?

Dr. TAYLOR. According to the State Health Bureau, about 20 cities.

Mr. KLEINFELD. Do you feel you are in a position to condemn the fluoridation of drinking water?

Dr. TAYLOR. I feel we are in a position to say that a city should wait until we have had time and other laboratories have had time to investigate this further.

Mr. KLEINFELD. What types of animals did you use in the experimental work described in your statement here—just mice?

Dr. TAYLOR. Just mice; two different strains of mice—one high cancer strain and one medium cancer strain.

Mr. KLEINFELD. Only two species?

Dr. TAYLOR. That is right, two varieties.

Mr. KLEINFELD. What kind of animals are you using in the new experimental work you are carrying on?

Dr. TAYLOR. We are still using mice.

Mr. KLEINFELD. And the same type of mice?

Dr. TAYLOR. The same type of mice.

Mr. KLEINFELD. Do you think it would be advisable to use some other animals in your experimental work?

Dr. TAYLOR. Yes; I do. I hope that other laboratories will take up this problem and work on it. Our main project, of course, as I mentioned before, is concerned with cancer research, and we do not feel that we can take too much of our cancer research time for this other problem. But we will go on however, with the lines we have already started and try to complete them.

Mr. KLEINFELD. Would it not be well to conduct similar experimental work on other animals such as hamsters?

Dr. TAYLOR. I think that hamsters would be very good. They seem to be more sensitive to fluorine possibly than mice.

Mr. KLEINFELD. Did the results of your experimental work indicate in any way that the addition of a compound like sodium fluoride to drinking water has any effect whatsoever on the incidence of cancer?

Dr. TAYLOR. No, our data doesn't indicate that.

Mr. KLEINFELD. On page 2 of your statement, the last paragraph, you indicate that your experiments show that while there was no change in the cancer incidence of the mice, which you just mentioned, cancer developed at an earlier age in the experimental group than in the control group.

Dr. TAYLOR. That is right.

Mr. KLEINFELD. As a consequence animals in the experimental group who developed cancer died at an earlier age than the control animals that acquired the cancer later on.

Will you describe that in some greater detail? What significance does that have, if any, so far as people are concerned?

Dr. TAYLOR. The data that we have indicate that a shortening of life span is the result. So that as far as people are concerned, on the basis of our mouse work, it would mean possibly 3 to 5 years in a human life. In other words, it would mean a shortening of the life span of the human population if these results apply to human beings.

Mr. KLEINFELD. You cannot carry those results over, can you?

Dr. TAYLOR. No; we cannot. It might be more severe and it might be less severe, or it might have no effect when people are concerned.

Before a particular drug goes on the market, it is tried first of all on animals, and then if it proves to be nontoxic for rats and mice, it may be tried in some experiments with voluntary human subjects.

Mr. KLEINFELD. You would have a much better picture one way or the other if you used two or more species of animals and fed them a diet which did not contain appreciable amounts of fluorine; is that not correct?

Dr. TAYLOR. The best test of all, from the standpoint of other than human, would be monkeys. They react similarly to human beings. However, they live longer than mice and it would not be possible to get the data in such a short time.

Mr. KLEINFELD. As I understand your statement, Dr. Taylor, you are not saying that the results of your experiments necessarily reflect what will happen to people if they ingest one part per million of fluorides in their drinking water?

Dr. TAYLOR. That is right.

Mr. KLEINFELD. Is it that you are suggesting merely that further study should be had?

Dr. TAYLOR. That is right.

Mr. KLEINFELD. That is the conclusion you come to?

Dr. TAYLOR. That is right. It simply puts a doubt where there has been no doubt and indicates the need for further study and more caution.

Mr. KLEINFELD. At the top of page 3 of your statement, Doctor, you say that both the controls and experimental animals appeared to be equal in health and vigor in the predisease state.

Can we say, then, from your observations it would seem that the addition of a fluoride to the diet of those mice did not result in a generally unhealthy appearance that was discernible?

Dr. TAYLOR. That is right. As far as we could observe from their behavior and handling and so on, you could not pick one group out from the other on that basis. They appeared to be identical.

Mr. KLEINFELD. At the top of page 4 of your statement you state:

> On the sole criterion of the effect on the teeth, it is assumed that equal concentrations of fluorine have equal biological effects regardless of whether it occurs naturally in the water or is added in the form of various fluorides. In other words, we are not to anticipate that the effect of fluoride on nondental tissues will be influenced by the presence or absence of various other chemical elements or by the type of combination between fluorine and other elements.

And you say that the real truth about this can only come from laboratory investigation.

As I understand this statement, Dr. Taylor, are you saying that not only can we not assume that the various inorganic fluorine-containing compounds are equivalent from the standpoint of total biological effects, but by the same token we cannot assume that naturally occurring fluorine in the water will be equivalent from the standpoint of total biological effects with all or any one of the inorganic compounds like sodium fluoride? Is that a correct statement?

Dr. TAYLOR. That is correct.

Mr. KLEINFELD. You are saying that unless we are certain that the effects upon the body of naturally occurring fluoridated water is exactly the same in all respects as artificially fluoridated water, statistics and investigations of populations in naturally fluoridated water areas are of no considerable value in considering the program of artificially fluoridating water. Is that your position?

Dr. TAYLOR. That is right. For instance, we have completed a survey of 42 different metal chlorides. We found that the effects of two metal chlorides together cannot be predicted from the known biological effects of them separately. And we found that the presence of other elements invariably changed the biological effects of the materials we were dealing with.

It is quite evident that the same principle would apply to the various forms of fluorides. Actually animal work should be undertaken with the fluorides as they occur naturally. There should be an experiment set up, for instance, along the lines that we did, testing naturally occurring fluorides and artificial fluorides, testing water from different sources.

The only way we can get an answer to that is to get it in the laboratory, we cannot sit back and say, "I don't think there is anything to it." That doesn't work where the issues are so serious.

Dr. MILLER. One question there, Mr. Counsel.

Then you would say that the addition of fluorides to water in some instances which contains more sulfur or calcium or magnesium or lithium or several other compounds—

Dr. TAYLOR. That is right.

Dr. MILLER. That the reaction of fluorides in that type of water would be different if you did not have the chemicals in the water?

Dr. TAYLOR. That is right. For instance, in Portland, Oreg., the water there can be used in batteries, just like distilled water. Putting sodium fluoride in such water might have one effect, and putting it in another place where conditions are different might have a different effect.

Dr. MILLER. Then cities contemplating the use of fluorides ought to know what chemicals they have in their water and what reaction might take place should the fluorides be used?

Dr. TAYLOR. Yes.

Dr. MILLER. Because if you had drinking water that smelled so much of sulfides it smelled like rotten eggs, or out in some area where there is a large amount of alkali, or where the water is very soft, the reaction would be different?

Dr. TAYLOR. That might be very important.

Dr. MILLER. Yes.

Mr. KLEINFELD. To simplify it, or perhaps this is an oversimplification—are you saying that if you want to find out the effect of compound X you must experiment specifically in the laboratory with compound X and not be confident with results of compound Y even though the two may be fairly closely related? Is that what you mean?

Dr. TAYLER. That is right.

Mr. KLEINFELD. Is your position in general accord with other scientists, would you say?

Dr. TAYLOR. I think so. I think if you were to take a panel of research scientists and put that proposition before them, they would be unanimous in saying that you would have to try it out before you could know what the results were going to be from a biological standpoint.

Mr. KLEINFELD. There might be some difference of opinion, I suppose?

Dr. TAYLOR. There might be difference of opinion as to how to approach the problem, but I think that all would agree that this information could only be obtained through laboratory work.

Mr. KLEINFELD. That is all I have.

Dr. MILLER. Thank you, Doctor, for your interesting and stimulating testimony.

Are there any other witnesses?

Mr. KLEINFELD. None today, no, sir.

Dr. MILLER. That committee will stand adjourned.

(Whereupon, at 11:55 a. m., the committee adjourned subject to the call of the Chair.)

CHEMICALS IN FOODS AND COSMETICS

THURSDAY, FEBRUARY 21, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess., continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 9:30 a. m. in room 429, Old House Office Building, Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney, of New York; Hedrick, of West Virginia; and Miller, of Nebraska.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will come to order.

Mr. KLEINFELD. Dr. Blayney is the first witness.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF J. R. BLAYNEY, D. D. S., PROFESSOR, DENTAL SURGERY, AND DIRECTOR OF THE WALTER G. ZOLLER MEMORIAL DENTAL CLINIC, UNIVERSITY OF CHICAGO

Mr. KLEINFELD. Will you give your name and address to the reporter?

Dr. BLAYNEY. J. R. Blayney, Chicago, Ill.

Mr. KLEINFELD. Dr. Blayney, what degrees do you hold?

Dr. BLAYNEY. I hold a bachelor of science, master of science, and doctor of dental surgery.

Mr. KLEINFELD. Where did you obtain your D. D. S. degree?

Dr. BLAYNEY. Northwestern University.

Mr. KLEINFELD. What year?

Dr. BLAYNEY. 1913.

Mr. KLEINFELD. What has your professional career consisted of since then?

Dr. BLAYNEY. Five years of general practice. Since 1918 I have been devoting my entire time to teaching and research.

Mr. KLEINFELD. Where have you been conducting this teaching and research?

Dr. BLAYNEY. For the first 18 years at the University of Illinois College of Dentistry and since 1936 at the University of Chicago.

Mr. KLEINFELD. What is your connection with the Evanston, Ill., dental caries study?

96568—52—pt. 3——32

Dr. BLAYNEY. I happen to be the director of that program.

Mr. KLEINFELD. As director, what generally are your duties?

Dr. BLAYNEY. I prepared the protocol which then was submitted to many other people for discussion and advice, selected the staff, keep a supervisory eye on all the activities, supervise the preparation of and very carefully check all reports.

Mr. KLEINFELD. When did this study commence?

Dr. BLAYNEY. The latter part of January 1946.

Mr. KLEINFELD. Will you please read your statement, sir?

Dr. BLAYNEY. The dental profession and the general public have demonstrated a growing interest in the fluoride content of communal water supplies since Margaret Smith and coworkers definitely established their relation to mottled enamel. At first fluorides were considered as an undesirable constituent; however, following the excellent epidemiological work of H. Trendley Dean and associates, we know that a minimal amount of naturally occurring flourine in a water supply is beneficial from the standpoint of tooth decay.

Klein has clearly demonstrated that children reared in an area where the water accidentally contains fluorides experience a lower caries prevalence rate than those reared in a nonfluoride area. He further has demonstrated that "the depressant effect of fluorides on caries may be approximately of equal potential for all the different types of teeth." However, because of the different degrees of susceptibility of different teeth "the resultant effect may be a variation in the percent reduction of caries among the different teeth." He estimates a reduction of about one-third in the caries attack rate in the lower molars.

These findings have changed materially the emphasis of fluoride studies, and we now recognize that fluorides in potable waters are a blessing in disguise.

The groups with which I have had the privilege of working have been studying the various aspects of the fluoride problems since 1938. These studies have shown that dental caries prevalence in white rats can be reduced materially by the addition of sodium fluoride to the diet without apparent detrimental effects upon the other tissues of the body.

Another study using approximately 100 dogs which were fed fluorides in the form of defluorinated phosphate, bone meal, and sodium fluoride in quantities to provide 5 milligrams of fluorine per kilo body weight over many months and extended in some cases to the third generation revealed no significant change in the hemoglobin, serum calcium and phosphorus ratio, coagulation time of the blood, and the rate of growth of the animals. The dogs on such diets revealed an increased fluorine content of their bones; however, the breaking strength of these bones was in the normal range when compared with control groups of dogs.

May I enter a parenthetical statement?

Mr. KLEINFIELD. Surely.

Dr. BLAYNEY. Coming down on the train, just to give you an illustration of the size of this dose of 5 milligrams per kilo body weight, I estimated that if a person weighing 125 pounds was going to drink water containing 1 part per million of fluorine that he would be required to drink something over 300 quarts per day in order to get the

same amount of fluorine these dogs were getting at 5 milligrams per kilo body weight.

It is of interest to note that the teeth of the animals receiving this amount of fluorine in the form of defluorinated phosphate or bone meal were better formed and the dogs had cleaner mouths than those animals receiving the basal control diet. Complete autopsies were performed on 53 of these dogs. In no instance did we find gross changes in any of the organs which could be attributed to the consumption of fluorides. Tissues were prepared for histological examination, and in the cases studied no evidence of degenerative change attributed to fluoride poisoning was found.

Following a survey of the dental conditions in Kempton, Ill., by our group where the fluoride content of the water appears to vary from 1.2 to 3 parts per million of fluorine, Dr. Paul C. Hodges and associates made a roentgenological survey of the skeletal system of 86 subjects with ages ranging from 7½ to 71 years and with an exposure to the community water ranging from none to 61 years. He states:

> In no instance did we observe the occurrence of a generalized sclerosis.

Dr. Hodges conducted a similar study in Bureau, Ill., where the fluoride content of the water contains approximately 2.5 parts per million of fluorine. There he examined 31 subjects with an age range from 18 to 78 years and with an exposure time of from 18 to 68 years. Here again, no sclerotic changes were observed in the skeletal system.

Our group has conducted a preliminary study of the distribution of fluorine in communal water supplies throughout the United States. This was accomplished by requesting the chief sanitary engineers of each State health department and the District of Columbia to provide us with a statement giving the fluorine concentration of the communal water supply of each city, town, and village in their respective areas. We received promptly a reply from each engineer giving us the most recent data obtainable. The analysis of the data revealed that the communities having the highest naturally occurring fluorine content in their water were found in nine States, with Texas, South Dakota, Ohio, Illinois, and Indiana taking the lead. There are approximately 5,646,897 people in the United States who have access to a communal water which contains 0.5 or more parts per million of fluorine. A total of 2,195,115 people are using water supplies which contain from 0.9 to 2.0 parts per million of fluorine. Some areas have water containing 5.0 or more parts per million of fluorine.

Insofar as I have been able to ascertain, the vital statistics of these areas do not reveal evidence of neoplastic, renal, or metabolic disease.

May I add another parenthetical statement?

Mr. KLEINFELD. Yes.

Dr. BLAYNEY. The day before yesterday I talked to Dr. Sagan, who is the chief of the Bureau of Vital Statistics of the State of Illinois.

I asked him if he knew of any difference in mortality rates or the frequency with which disease appears in the different parts of the State, particularly those parts which contain fluorides as compared to those parts that do not.

He told me that he had been making a study of that and, while their data is not completely analyzed, at the present time it is far enough along for him to state that they have observed no difference.

The recent publicity regarding the treatment of water supplies in an effort to reduce the prevalence of tooth decay has caused many people to conclude that through the addition of fluorides to the water a new element is being placed in our diet. I would like to point out that this is not the case.

We have analyzed foods very common to our diet which were purchased on the open market and have found that they contain fluorine in amounts varying from 0.14 to 11.2 parts per million. Therefore, the addition of fluorine at approximately 1.0 part per million to the water is not introducing a new element into our dietary.

With assurance from the above studies and others that the consumption of a reasonable amount of fluorine was not harmful to body tissues, we were pleased to accept the invitation of Dr. Winston H. Tucker, health commissioner of Evanston, Ill., to cooperate in conducting a study on Evanston school children to determine the value of adding sodium fluoride to the communal water supply for the control of tooth decay. The citizens of Evanston were told that we did not know what the results would be, that is was necessary to conduct such a study in several municipalities in order to obtain the answer to this question as soon as possible, that tooth decay in our people is a major public-health problem, and that it is vital to the national health and welfare to develop some method for the reduction of caries which is applicable to large population groups.

The details of the program were carefully arranged so as to secure ample data while the study is in progress. It was decided to add sodium fluoride to the water so as to produce a level of 1.0 part per million of fluorine. The study was instituted in January 1946 and projected through 1961. This time is required in order to provide one 14-year-old group of children whose entire life, both pre- and postnatal, was under the influence of fluoride-containing water. The sodium fluoride was added to the water on February 11, 1947.

The data compiled by the examination of the 6-7-8-year-old children in 1951 or after four complete years of fluoridation are now being analyzed. The figures now available indicate that there has been no reduction in the caries prevalence rates of the deciduous dentition. However, quite to the contrary, they show a reduction in caries of the first permanent molars by 39.5 percent, a figure very close to that which Klein estimated for the lower molars in what he calls accidentally fluoridated water. We have found also an increase of 23 percent of caries-free first permanent molars.

That is in the 6, 7, and 8-year-old children in 1951.

The DMF—that is, the decayed, missing, and filled—rate of the permanent teeth of this group of children when compared with the base-line figures of 1946 has decreased 48 percent after 4 years of water fluoridation. These figures are very stimulating, however, they are not exactly in accord with those of some other workers.

One question which we hope to answer in the near future is: Does the water which naturally contains fluorides contain some other trace element which is not found in the fluoride-free waters, and if so, what is the possible effect of such a trace element on the rate of caries attack? We are now proceeding to make spectrographic analyses of both types of water in the hope of providing some further information.

In conclusion, the present opinion of our research group is:

The addition of 1.0 to 1.5 parts per million of fluorine to a communal water will not endanger the health of human beings.

It is essential that the studies in the several communities now under way be continued in order that we may ultimately know the exact benefits which accrue from water fluoridation.

All studies are reporting very encouraging results in the reduction of caries. Please note the word is reduction and not stop or prevention.

If municipalities wish to add fluorides to their water supplies for the reduction of tooth decay they should thoroughly understand that the investigative work on the problem has not yet been completed.

I have a list of references to my statement.

(The references referred to are as follows:)

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3. *Dean, H. Trendley, Jay, Philip, Arnold, Francis A., Jr., McClure, Frank J. Elvove, Elias.* Domestic Water and Dental Caries Including Certain Epidemiological Aspects of Oral L. Acidophilus. Reprint No. 2073, Public Health Reports, vol. 54, No. 21, May 26, 1939, pages 862–888.
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11. ——— The Evanston Dental Caries Study VIII. Fluorine Content of Vegetables Cooked in Fluorine Containing Waters. J. Dental Res., vol. 30, 1951, pages 676–681.
12. *Largent, E. J., Machle, W., and Ferneau, I. F.*, Fluoride Ingestion and Bone Changes in Experimental Animals. J. Ind. Hyg. Toxicol. vol. 25, 1943, page 396.

Mr. KLEINFELD. Dr. Blayney, on the first page of your statement, at the bottom of the page, you discuss a study where you used approximately 100 dogs which were fed fluorides in a certain form.

Do you know how long that experiment was carried on?

Dr. BLAYNEY. Well, that was carried on for several years. I just cannot give you the exact time but we had some dogs that were in the third generation.

To start with, we obtained three pregnant females, from the pound and another person contributed another pregnant female. So, we had four pregnant females and we developed our colony; so, we were carrying it on for quite some time.

Mr. KLEINFELD. And were your experiments conducted on the offspring of those dogs?

Dr. BLAYNEY. They were conducted on the offspring. The mother dog had the diet and the offspring had the very same diet. It was carried on continuously.

Mr. KLEINFELD. Over the life span of the original dogs and the offspring?

Dr. BLAYNEY. Yes, sir.

Mr. KLEINFELD. On page 2 of your statement, Dr. Blayney, in the last sentence of the first paragraph, you say:

Tissues were prepared for histological examination and in the cases studied no evidence of degenerative change attributed to fluoride poisoning was found.

Were any changes found?

Dr. BLAYNEY. Well, sometimes the dogs had worms and died. Sometimes they had pneumonia and distemper and many other conditions which caused the death of the animal; yes. But, there was nothing that was attributable to fluorides.

Mr. KLEINFELD. These were natural losses?

Dr. BLAYNEY. Yes, sir; certainly. When you have that many dogs in the colony you are going to have losses.

Mr. KLEINFELD. In the following paragraph, Doctor, you say that:

Following a survey of the dental conditions in Kempton, Ill., by our group where the fluoride content of the water appears to vary from 1.2 to 3.0 parts per million of fluorine, Dr. Paul C. Hodges and associates made a roentgenological survey of the skeletal system of 86 subjects.

Was natural fluoride appearing in the water there?

Dr. BLAYNEY. Yes.

Mr. KLEINFELD. Not sodium fluoride?

Dr. BLAYNEY. It was naturally occurring.

Mr. KLEINFELD. And similarly, with regard to the study that Dr. Hodges conducted in Bureau, Ill., was that a study of water where fluoride appeared naturally?

Dr. BLAYNEY. Yes, sir.

Mr. KLEINFELD. On page 3, Dr. Blayney, you say:

Insofar as I have been able to ascertain the vital statistics of these areas do not reveal evidence of neoplastic, renal, or metabolic disease.

Dr. BLAYNEY. I think that a word was left out, "increased." It should read:

do not reveal increased evidence of neoplastic, renal, or metabolic disease.

Mr. KLEINFELD. Evidence of increased?

Dr. BLAYNEY. Yes, sir.

Mr. KLEINFELD. Do you know if clinical studies, and examinations were made of considerable numbers of persons?

Dr. BLAYNEY. Yes. Clinical examinations were made on those people but not by Dr. Hodges. He consulted with the physicians in the town and discussed the matter with them, people who had been residing there and taking care of the population.

Dr. Hodges is a roentgenologist. The films that were produced in these two communities were brought back to the city of Chicago. A group was called together consisting of roentgenologists in the city and orthopedic surgeons and they examined the films and discussed them for the purpose of determining if there was evidence in the films of osteosclerosis that was attributable to the consumption of fluorides.

This was not Dr. Hodges' opinion, it is the opinion of a group of roentgenologists and orthopedic surgeons, people who are dealing with these things, who reviewed all the films to reach a conclusion.

Mr. KLEINFELD. Was any report of the clinical examinations published?

Dr. BLAYNEY. No; not to my knowledge.

Mr. KLEINFELD. On the same page, Doctor, you say that you have analyzed foods common to their diets.

Dr. BLAYNEY. Yes.

Mr. KLEINFELD. And you found that they contained fluorides in varying amounts.

Dr. BLAYNEY. Yes, sir.

Mr. KLEINFELD. That would vary from small percentages, I suppose, to very considerable percentages in foods like fish?

Dr. BLAYNEY. Yes, sir.

Mr. KLEINFELD. You say in your statement:

> Therefore, the addition of fluorine at approximately 1.0 parts per million to the water is not introducing a new element into our dietary.

Now, do you know whether the fluoride that you find naturally in foods such as fish is there in the form of sodium fluoride?

Dr. BLAYNEY. I do not know.

Mr. KLEINFELD. Is there a difference, Dr. Blayney, in the solubility of the fluoride found naturally in foods and the solubility of sodium fluoride which, as I understand, is ordinarily used in fluoridating water, if you know?

Dr. BLAYNEY. I do not know, sir?

Mr. KLEINFELD. You say on the same page:

> With assurance from the above studies and others that the consumption of a reasonable amount of fluorine was not harmful to body tissues we were pleased to accept the invitation of Dr. Winston H. Tucker, health commissioner of Evanston, Ill., to cooperate in conducting a study.

Doctor, are you familiar with the reports put out by the people conducting the Newburgh-Kingston caries-fluorine studies?

Dr. BLAYNEY. Yes, sir.

Mr. KLEINFELD. The last report that I have concludes as follows:

> The results thus far in the study have disclosed no deleterious systemic effects from the ingestion of fluoride in drinking water in the dosage employed.

This seems to be in accord with your opinion, Doctor.

Then they go on to say:

> It must be emphasized, however, that a longer period of observation is required before final conclusions can be drawn. The possibility of demonstrating cumulative effects of fluoride in the final years of the 10-year study cannot be eliminated at this time. More refined techniques may also be available in the future in studying pertinent aspects of the problem.

Apparently, there is some difference then between your opinion and theirs with respect to how definite you can be at this time concerning the possible cumulative toxicological effects of fluoride.

Dr. BLAYNEY. I do not believe there is. I would interpret that statement to mean that a research problem is never complete. You can always keep looking on different problems related to your major point of investigation. I do not think there is a major difference in our opinion.

Mr. KLEINFELD. Well, you do believe, do you not, Doctor, that you should conclude this 15-year experimental period before you reach definite conclusions on how the incidence of dental caries is reduced?

Dr. BLAYNEY. I believe it is very essential to have evidence of the effect on the entire life of the individual, both prenatal and postnatal. That is the reason for the 15 years.

Mr. KLEINFELD. And you feel you cannot draw a definite conclusion as far as the reduction of the incidents of dental caries is concerned until the 15 years are concluded?

Dr. BLAYNEY. I think that that would bring much more valuable data. We get trends, as I fairly frequently call it, we get trends, but the ultimate will come when we have one group of children who have been exposed both prenatal and postnatal until they reach the age of 14, postnatal.

Mr. KLEINFELD. You mean exposed to the addition of sodium fluoride in drinking water?

Dr. BLAYNEY. Yes, sir.

Mr. KLEINFELD. As to the experimental period, do we understand that the experimental period of any of the other cities has been completed?

Dr. BLAYNEY. Not to my knowledge.

Mr. KLEINFELD. Doctor, when you set up your study, was it designed specifically to determine not only whether the incidence of dental caries would be reduced, but whether the addition of certain fluorides as compounds would have any deleterious nondental physiological effects on the population?

Dr. BLAYNEY. The children in the city of Evanston schools are required to receive a health examination four different times throughout their residence in the school, from the first grade through to the completion of high school.

The physicians that are making these examinations are watching for any possible effect that might be manifested in any of the children.

These examinations are running regularly and each child throughout his period of public school residence will have these four different examinations. That is required, I believe, by the State of Illinois.

Mr. KLEINFELD. So that you can say that when your study was begun you wanted to study two specific things; first, the reduction of the incidence of dental caries, and, second, the possible toxicological effects?

Dr. BLAYNEY. Yes, sir.

Mr. KLEINFELD. And you will not know that until your experimental period is over, is that not correct?

Dr. BLAYNEY. It will take that time before we know.

Mr. KLEINFELD. Do your studies contemplate regular examinations of older groups of the population?

Dr. BLAYNEY. Dentally?

Mr. KLEINFELD. Medically as well as dentally.

Dr. BLAYNEY. No. We are not dealing with the older population groups.

I might say there is one thing we do. We obtain teeth from the Evanston dentists that have been removed for examination for their fluoride content. At frequent intervals we obtain sections from a certain portion of the crest of the ilium taken at necropsies that are conducted in the Evanston hospitals so that the fluoride content can be determined in the length of time that that individual has been exposed to fluoride-containing water.

Mr. KLEINFELD. But it is not a definite part of the program you set up?

Dr. BLAYNEY. Not a complete physical examination of adults; no, sir.

Mr. KLEINFELD. Are more specific examinations being made of older people who are suffering from kidney disorders?

Dr. BLAYNEY. In Evanston?

Mr. KLEINFELD. Yes, sir.

Dr. BLAYNEY. Not to my knowledge. I might say that before this program was instituted, both the medical and dental professions cooperated and the medical profession is aware of this program and I would assume that they would be quick to recognize any change that might occur since the institution of this program.

We had several very extended conferences. We have an advisory committee. I requested that an advisory committee which is composed of both physicians and dentists be formed with which we discuss these things.

So, the medical profession is well informed concerning the program there.

Mr. KLEINFELD. As I understand, Doctor, you are watching children rather carefully and regularly.

Dr. BLAYNEY. Very carefully.

Mr. KLEINFELD. Particularly in trying to determine what the incidence of dental caries is, whether there has been a reduction and if so to what extent.

Dr. BLAYNEY. That is right.

Mr. KLEINFELD. But you are not watching the medical aspect of the possible effects on the older people to the same extent?

Dr. BLAYNEY. Not on the older people.

Mr. KLEINFELD. Doctor, why was a 15-year period picked in the Evanston experiment?

Dr. BLAYNEY. Because we wanted to have the child reach 14 after the fluoridation of the water so we would have both prenatal and postnatal exposures.

Mr. KLEINFELD. Do you think that period of time is necessary before you can reach a conclusion?

Dr. BLAYNEY. I think it is advisable.

Mr. KLEINFELD. On page 4, Doctor, at the end of the second paragraph, you discuss figures with respect to dental caries and you say that the figures which you cite are stimulating but that they are not exactly in accord with those of some other workers.

Dr. BLAYNEY. That is right.

Mr. KLEINFELD. Why is that?

Dr. BLAYNEY. Well, I think some other workers have recorded a reduction of caries in the deciduous teeth in less time than what our study has been going on. May I continue that?

Mr. KLEINFELD. Surely.

Dr. BLAYNEY. I assume that the reason we had not experienced reduction in the deciduous teeth and have found a reduction in the permanent teeth is because the children we have examined had formed all of the crowns of the deciduous teeth by the time the fluorides went into the water and most of the deciduous teeth had even erupted into the mouth at the time the fluorides went into the water. Now, that is not true of the permanent teeth.

We are studying permanent teeth that had completed their calcification and then had what we call a postformative but preeruptive exposure before they came into the mouth.

Now, I think that is where the benefit lies and in the future we expect to find a reduction of caries in the deciduous teeth.

The deciduous and permanent teeth in our study are not exactly comparable in their exposures.

Mr. KLEINFELD. The deciduous teeth are the first nonpermanent teeth?

Dr. BLAYNEY. That is right, they are the first set of teeth or the milk teeth.

Mr. KLEINFELD. In conducting examinations of the teeth of children without the use of X-rays, will not many examiners differ in their reports or conclusions?

Dr. BLAYNEY. Yes; I think they will. I think that you cannot help but find cavities in the X-ray film that were too small to be detected from the clinical examination.

Mr. KLEINFELD. In the cities you have studied so far with respect to dental caries, can you say that there has been a reduction in the incidence of dental caries to the extent of 65 percent?

Dr. BLAYNEY. Our figures show that the decrease is, in the decayed, missing, and filled teeth, at the present time approximately 48 percent.

Mr. KLEINFELD. Are you following fairly closely the reports put out by other cities?

Dr. BLAYNEY. I certainly try to.

Mr. KLEINFELD. Do you know of any reports which indicate a reduction of dental caries of 65 percent?

Dr. BLAYNEY. As I recall, I believe it was 60 percent, but I am not—I just could not say offhand what it was. There were some reports higher than ours. That is the reason I said our figures did not agree and that I anticipated our figures would not agree, because of the difference in techniques used.

Mr. KLEINFELD. There have been some reports indicating fairly low decreases and other reports which indicate much higher decreases. You say the reason for that difference is the difference in dental technique. What is the reason for that?

Dr. BLAYNEY. Well, first of all, I think the facilities you have at your disposal when you are making the clinical examination is a factor. Again, I think the time allocated for each clinical examination, too, is important.

Dr. MILLER. I would like to ask you a question or two.

Speaking of the reduction of dental caries by the application of fluorides, does that cover the mass ingestion of fluorides in water or the topical application in the dentist's office?

Dr. BLAYNEY. That is the placement of fluoride in the communal water supply.

To carry your point a bit further, in our records we know every child that has had topical application in the dental office. But because we have the wholehearted interest and cooperation of the dental profession in Evanston, it is only in those extreme cases where there exists a very high degree of susceptibility that any of the dentists use topical applications in Evanston because they do not want to put in variables.

Dr. MILLER. Do you have any records of the incidence of caries in children where the dentists used topical applications?

Dr. BLAYNEY. I have had no personal experience. I know there is literature on that, where they ascertain that approximately, in mass applications, around 40-percent reduction is shown; but I have had no personal experience.

Mr. KLEINFELD. Dr. Blayney, at the bottom of page 4 you say:

> One question which we hope to answer in the near future is: Does the water which naturally contains fluorides contain some other trace element which is not found in the fluoride-free waters, and if so, what is the possible effect of such a trace element on the rate of caries attack?

Do you think it is important to obtain that information?

Dr. BLAYNEY. I do not know. I believe that from a scientific standpoint we should know it. Whether it is important or not, I do not know. Time only will tell.

Mr. KLEINFELD. Does anybody know it, as far as you know?

Dr. BLAYNEY. I have not been able to find it in the literature.

Mr. KLEINFELD. Do we know as a scientific fact the form in which fluoride appears in naturally fluoridated water?

Dr. BLAYNEY. It is my impression that the people that make water analyses and estimate the amount of fluoride in it, estimate it as occurring as sodium fluoride.

Mr. KLEINFELD. Does that mean, Doctor, that they have ascertained by analysis that the fluoride is in the water because of the presence of sodium?

Dr. BLAYNEY. That is my assumption.

Mr. KLEINFELD. Has that been reported, as far as you know?

Dr. BLAYNEY. Well, the waters that have been examined, yes. I said that there were over 5 million people in the United States that were getting water which naturally contains fluoride——

Mr. KLEINFELD. Well, there are a number of fluoride compounds, of course.

Dr. BLAYNEY. Oh, yes.

Mr. KLEINFELD. Maybe I have not made my question clear. I am wondering whether it has been definitely ascertained that the fluoride which you find in water in localities like Colorado Springs got into the water in the form of sodium fluoride or some other fluoride compound.

Dr. BLAYNEY. It is my impression that the chemists when they analyze water to determine the different constituents of the water and then they estimate that it is possible for these elements to occur in certain combinations.

Mr. KLEINFELD. In other words, Doctor, when the chemist analyzes the water he will find that various things are present in the water, including fluorine.

Dr. BLAYNEY. That is right.

Mr. KLEINFELD. He will not necessarily find further that the fluorine which he finds got there because of the presence at some time or other of a particular fluoride compound?

Dr. BLAYNEY. My training has not been very extensive along the lines of chemistry but I would assume that it is an estimate that it occurs as such; but I am not a chemist.

Mr. KLEINFELD. Do you know, Doctor, whether any studies have been made to determine whether any portions of the population of Evanston have suffered any allergic effect from the fluoridation of the water?

Dr. BLAYNEY. I know of none. There have been no complaints, I know of none.

May I say that the citizens of Evanston have been most cooperative from the individuals down through different organizations, and all of the schools, and it has been a great pleasure to work with them. I have had no reports of that type.

Mr. KLEINFELD. Are you, Doctor, as completely enthusiastic about the beneficial results of the fluoridation of drinking water as many of the other workers?

Dr. BLAYNEY. That is a hard question to answer. I would say that probably I am a bit more cautious than some.

As I said in my conclusions, I cannot stand before a community and say that they must put fluorides in their water.

I say that if they wish to do so I see no harm that can accrue, no bodily harm, and that they must recognize that the data that we have before us is encouraging, but the final statistics are not yet available.

If they want to do it on that basis, I believe there is very good evidence that there will be a reduction. But I absolutely refuse to use the words "stop," or "prevent," because I do not think it is going to do either.

Mr. KLEINFELD. Doctor, I have here a letter dated January 16, 1952, addressed to Mrs. Marion E. Lyon of Geneva, N. Y., signed by J. R. Blayney, D. D. S., director.

Let me show that to you and ask you whether you wrote that letter and signed it.

Dr. BLAYNEY. Well, that is my signature.

Mr. KLEINFELD. It is a short letter. I wonder if you would read it to the committee.

Dr. BLAYNEY. The whole thing?

Mr. KLEINFELD. Yes.

Dr. BLAYNEY (reading):

MRS. MARION E. LYON,
415 South Main Street, Geneva, N. Y.

DEAR MRS. LYON: I am pleased to acknowledge the receipt of your letter of January 1 requesting information regarding the Evanston dental caries study.

I am pleased to state that careful physical examinations on Evanston children have shown no ill effects from the administration of 1.0 parts per million of sodium fluoride in the community water supply. You may be sure that I was thoroughly convinced from previous animal studies that such minimal amounts of fluorine would not be harmful to humans.

It is impossible to give you a full statement regarding the value of sodium fluoride in the reduction of tooth decay at this early date. The Evanston study is planned for a 15-year study, which I believe is sufficient time to permit the proper evaluation of this procedure. Inasmuch as all of the deciduous teeth of the children which we have so far examined had erupted prior to the fluoridation program, it is not expected to find a marked reduction in the incidence of

caries. Our findings to date indicate that when the deciduous teeth are studied none of our children have shown a reduction in the incidence of tooth decay. The results dealing with the permanent teeth have shown a definite trend in the reduction of this ubiquitous disease. Since many of these teeth have erupted after the placement of fluorine in the communal water it appears to indicate that the greatest benefit can be expected when the fluorine is administered during the formative period of the teeth.

I do not know at this writing whether fluorine will really prevent the development of a certain amount of tooth decay or if it will merely retard the development. I cannot be as enthusiastic regarding the fluoridation of communal water supplies as many others appear to be. I am of the opinion that we must have more evidence before definite statements can be made. I sincerely hope that the fluoridation program will be as beneficial as those who are enthusiastic about it anticipate. However, to date no one has sufficient evidence that will permit me to make such blank statements.

There has been such a demand for reprints of our published material that our supply has been exhausted. However, I am enclosing a list of our publications which should aid you in reviewing material. This will give you the data we have collected and the reasons for our caution which we recommend at the present time.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Doctor, on page 3 of your statement, down about the middle of the page, you say:

> We have analyzed foods very common to our diet which were purchased on the open market and have found that they contain fluorine in amounts varying from .014 to 11.2 parts per million of fluorine.

Can you name some of those foods that contain the greatest quantities of fluorine?

Dr. BLAYNEY. The highest one, the 11.2, happens to be a breakfast food, Pablum.

The CHAIRMAN. That is a baby food; is it not? Isn't Pablum a trade name?

Dr. BLAYNEY. I cannot answer that.

The CHAIRMAN. What amount of fluorine is in it, would you say?

Dr. BLAYNEY. Well, the fluoride content of Pablum comes from the bone meal which is added in order to provide the calcium, phosphorus, and so forth, which they thought was advantageous for the young child to have and the fluoride that is in the bone meal is carried over with the calcium and the phosphates.

The CHAIRMAN. Is that readily assimilated by the system of an infant?

Dr. BLAYNEY. I have not made any studies. I cannot answer that question.

The CHAIRMAN. You spoke in your statement of fluorides naturally appearing in waters. In what parts of the world, if you know, do fluorides appear in the water?

Dr. BLAYNEY. I do not know. I cannot answer that.

also occur in Europe. Italy has a lot of them.

The CHAIRMAN. What about Great Britain and Scotland?

Dr. BLAYNEY. I do not know. I cannot answer that.

The CHAIRMAN. Doctor, when a tooth decays, does it decay from the inside out or from the outside in?

Dr. BLAYNEY. From the outside in. The initial lesion of dental caries is on the enamel surface.

The CHAIRMAN. Well, then, does the fluoride have an effect internally or does it have a good effect from the passing of the water through the mouth?

Dr. BLAYNEY. I do not know the manner in which fluoride acts and I do not believe anybody knows the exact nature by which it acts. We have a few theories.

The CHAIRMAN. Yes.

Dr. BLAYNEY. But they are only theories at the present time.

The CHAIRMAN. Well, some dentists, of course, paint the teeth with fluoride; is that not right?

Dr. BLAYNEY. Yes, sir. One of the theories that you might say is universally accepted is that the fluorine ion combines with the hydroxyapatite, the crystal in the enamel, to form a fluorapatite. The presence of the fluorine in the crystal—the fluorapatite is less soluble in an acid medium than the hydroxyapatite, so the result has been that the addition of sodium fluoride to the outer surface of the tooth causes an ionic exchange rendering that very outer surface less soluble in an acid.

The CHAIRMAN. In view of the statement you make about Pablum having a greater quantity of fluorine caused by the fact that bone meal is added to it, would that not indicate that the bones themselves contain a considerable portion of fluorine?

Dr. BLAYNEY. Yes, sir. All of our bones contain fluoride. My bones contain fluoride. Everybody's bones contain fluoride.

The CHAIRMAN. So you would think that internally it would fortify the bone?

Dr. BLAYNEY. I think that. Please note that I say, "I think." I do not know.

The CHAIRMAN. Well, I am asking that question because I do not know, either.

Dr. BLAYNEY. I believe that the presence of fluorine in the body tissue—as the tooth crown is being formed, that the fluorine is deposited in the enamel crystal and that is why we are not getting a reduction in the deciduous teeth of children, because the enamel formation had taken place already, while at the same time we are finding reduction in the permanent teeth.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. Doctor, have there been any tooth pastes on the market with fluorine that you know of?

Dr. BLAYNEY. Oh, yes.

Dr. HEDRICK. Do you know how much?

Dr. BLAYNEY. Well, I do not know. People have been advocating dentifrices containing fluorine. The amounts of the fluorine in them, I do not know.

Dr. HEDRICK. Who is responsible for the first discovery of the value of fluorine in tooth decay?

Dr. BLAYNEY. I think that belongs to Dr. H. Trendley Dean and his associates in the United States Public Health Service in their studies of the endemic disease of fluorosis, that is mottled enamel.

They observed that the children in those communities had different types of mouths than the children in other communities. I would say it is Dr. H. Trendley Dean and his associates.

Dr. HEDRICK. In what area was that detected first?

Dr. BLAYNEY. Well, their major work was done in Galesburg, Ill., as a fluoride area, Quincy, Ill., as an nonfluoride area; Aurora as a fluoride area and Elmhurst as a fluoride area; Oak Park as a nonfluoride area and Evanston as a nonfluoride area. They have worked

in many different communities. Now, those are all right at home. I was reared at Galesburg and I know the story there.

Dr. HEDRICK. Do you find more fluorine in well or spring water; does deep water have more?

Dr. BLAYNEY. As a rule you will find in this part of the country the fluorides in the deep wells.

Dr. HEDRICK. How expensive would fluorination be for a community, say a city of 50,000 people? What would be the cost?

Dr. BLAYNEY. Well, in Evanston up to date it has been costing about 11 cents per capita per year.

Dr. HEDRICK. What is the initial cost to put in the equipment?

Dr. BLAYNEY. Well, the cost of the equipment has gone up somewhat. At the present time the type we have in Evanston, which would be a dry-feed Omega machine, I believe they cost around $3,000 now. Ours was considerably less.

The installation prices are not high and there are many different types of machines and methods that can be employed at varying costs, depending upon the size of the community.

Dr. HEDRICK. Well, taking a town of 50,000 people, for instance, about what would it be?

Dr. BLAYNEY. Well, that would depend upon whether they had one central filtration plant or if they had their water from several sources.

I happened to be in Spokane last spring when that was being considered there. I believe it would be very difficult in Spokane at the present time because they get their water from—oh, I am afraid to say the number, but it is an amazing number of areas that the water of Spokane comes from.

However, in Chicago and many communities where they get their water from one or two or only a few places, I think it can be done on the basis of a few cents per year per capita.

Dr. HEDRICK. That is all.

The CHAIRMAN. Dr. Miller?

Dr. MILLER. Dr. Blayney, your testimony has been interesting. I would like to ask a question or two.

I will ask you whether you feel that, with our present knowledge of what fluorine will do in water, you believe it should be universally advocated and pressed for use in all cities in the drinking water?

Dr. BLAYNEY. I would say if a community wants to do it, that it is perfectly all right.

However, I could not stand before them and tell them the exact benefits that they may expect.

Dr. MILLER. Inasmuch as there are so many unknown quantities in the question, would you say there was no danger about it?

Dr. BLAYNEY. I would say that as far as any evidence has brought out to the present time, there is no danger to our health and welfare.

Dr. MILLER. Would you be in a position to say that at the present time, if you do not know the exact role that fluoride would play in modifying caries in the teeth? Do you know the exact role that fluorine plays?

Dr. BLAYNEY. If you mean the method by which it accomplishes that, I would say that I do not know. If you mean by the exact role the amount of reduction that we may experience, I can merely cite our figures which I have just obtained this past week in Evanston for

the permanent teeth. It has reduced the decay in missing and filled teeth at the rate of about 48 percent per 100 children.

Dr. MILLER. And yet you say on page 5 of your statement in the last paragraph:

> If municipalities wish to use fluorides in their water supplies for the reduction of tooth decay they should thoroughly understand that the investigation work on the problem has not yet been completed.

Dr. BLAYNEY. Yes, sir. I believe that.

Dr. MILLER. In other words, there are many unknown factors that have not been answered?

Dr. BLAYNEY. The principal unknown factor, as I see it that has not been answered, is how much reduction they can expect.

Dr. MILLER. Let me ask you, what would be the effect of adding fluorides in, say, certain types of spring waters that have a lot of sulfide in the water—you know, the kind that the worse it smells, the more good one thinks it is going to do him—they contain sulfides and phosphates and calcium and, I suppose, chlorides.

Is there a chemical reaction when you put fluorides in with these other salts?

Dr. BLAYNEY. I am not a chemist.

Dr. MILLER. You do not know?

Dr. BLAYNEY. I cannot answer that question.

Dr. MILLER. Would you be in a position to say what would happen through the use of water that has a lot of fluoride, when you came to using that water for, say, preserving foods, making wine or beer or things of that type?

Dr. BLAYNEY. From the standpoint of industry in the different areas where water contains fluorides or where fluorides have been added, I know of only one complaint.

That is from a community in one of the Carolinas. The ice-manufacturing people there had difficulty with their ice cracking and fluoridation was suspended for a month or two. They communicated with other ice manufacturers and found out there is a method which they can use and now they are again fluoridating the water and the ice is not cracking.

That is the only industrial complaint that I know of.

Dr. MILLER. We had some testimony a couple of days ago, February 19, I believe it was, from two scientific investigators, Dr. Robert S. Harris, of the Massachusetts Institute of Technology, Cambridge, Mass., and also Dr. Alfred Taylor, of the Biochemical Institute of the University of Texas.

They raised some rather interesting questions as to the need and the results that might come to individuals by the use of fluorides over a long period of time and they felt that we were going into it a little too hurriedly because of the unknown factors and consequences in the individual.

Have you any comments on that, or did you read their testimony, or are you familiar with it?

Dr. BLAYNEY. I have not read their testimony. I am in a measure familiar with their thoughts, but I just cannot follow their thinking.

Dr. MILLER. Well, they are scientists.

Dr. BLAYNEY. That is right; let them be.

Dr. MILLER. You and I, one as doctor and one as a dentist, may be a little bit vague——

Dr. BLAYNEY. Let me say this. I have reviewed the vital statistics and made an effort to find out from people that should know.

Now, when there are over 5 million people in the United States that have been consuming fluorinated waters over a long period of time and these things do not show, I am very much inclined to be a skeptic regarding their statements.

Dr. MILLER. I think that one of them even went so far as to say that fluorides are used as rat poison.

Dr. BLAYNEY. Oh, sure. That is ridiculous, to make such an analogy.

Dr. MILLER. Of course, you and I may have used strychnine sulfate and thereby saved some lives, and that is also a poison.

Now, there is quite a controversy over fluoridation of the water in the District of Columbia, which is appearing in our newspapers. Let me read you the following:

> The controversy over fluoridation was on again today as preparations went ahead to treat the District's water supply, probably starting this spring.
>
> Most District residents could only speculate as the experts differed among themselves over the possible effects of adding fluoride to their drinking water as a tooth-decay-prevention measure.
>
> But Commissioner F. Joseph Donohue announced he was not disturbed by reports on Capitol Hill yesterday that the process could cause a harmful effect among some persons drinking the water.

Now, I might say that a Commissioner always has to know everything about everything, they are very much like a Congressman in that respect [laughter]. Of course, being just a layman and a lawyer, he thinks naturally that he would know all about fluoridation, and so we can take his word that the people need not worry about what happens when they take fluorides because, after all, he is presumably an expert on everything.

Now, he also said, quoting:

> Mr. Donohue said studies indicate millions of persons are drinking and have been drinking water containing more fluoride than is proposed for addition to the District's water, and medical authorities have not found any harmful effects except sometimes the appearance of mottled tooth enamel where fluoride was present in large amounts.

Now, are we getting any mottled teeth in Illinois, Doctor?

Dr. BLAYNEY. In Evanston?

Dr. MILLER. In Evanston.

Dr. BLAYNEY. We have not noted an increase in the amount of mottling.

Dr. MILLER. You have not noted it?

Dr. BLAYNEY. No, sir.

Dr. MILLER. Now, Doctor, this committee also in its studies has found that there are several hundred chemicals being used in foods, and with a number of them we do not know the exact effects upon the human being when they are used. I think there are some 700 chemicals knocking at the door of the food industry to be used.

Now, fluoride, I guess, is a chemical which might be used in some of the foods, I am not sure, but I suppose that all of us would like to know what effect they would have upon the human being before they were permitted in extensive use, is that not true?

Dr. BLAYNEY. I think so; certainly.

Dr. MILLER. Have you any suggestions to make to this committee as to recommendations to make, when we come to it, on fluoridation,

whether we should give cities all over the country the green light or whether we should put up the red light or, even, a yellow light saying, "Let us go a little slower until we find out what is going on"? What would you recommend?

Dr. BLAYNEY. I would say that since so many communities, you might say all major communities, are interested in this problem, that if they wish to consider the placement of fluorides in their water they should be told the pros and cons, just about like I have attempted to set forth my thoughts here and if the city council is responsible for that, or whatever the body may be, must assume the responsibility. I spoke before the Park Ridge Council the night before last. They were considering it and in summation they asked me a question just about like that.

I used a phrase that I use with students every now and then. I said, "Gentlemen, you must assume the role of a philosopher. Philosophy is perspective. Science is knowledge. Without knowledge the perspective is wrong or very likely to be wrong. Without philosophy the perspective may be distorted."

It is like using a microscope or a binocular, you have to look too far and too close before you get the exact perspective.

Dr. MILLER. This newspaper article also says:

> Dr. Taylor testified 20 Texas cities were holding up plans for fluoridation of their drinking water as a result of Texas experiments on the effect of adding sodium fluoride to the drinking water of mice.

Now, if these cities are holding up the fluoridation of water pending the conclusion of studies, should we censure those cities for asking for more information or any city or city council which says, "Let us wait until some more information is available; waiting will do no harm and maybe it will do some good"?

Dr. BLAYNEY. Well, in my opinion, no harm is being done.

I think the information that is available on any health problem should be readily forthcoming to any community that wants it.

Dr. MILLER. Do you know what experiments, if any, the American Dental Association, the American Medical Association, and the Public Health groups have carried out in coming to the conclusions they have, that it ought to be used and used now?

Dr. BLAYNEY. I think the United States Public Health Service has carried on investigation on this problem for many years and they are to be completed.

Dr. MILLER. Can you cite any publications that there are on it?

Dr. BLAYNEY. Oh, there are numerous ones. The work of McClure, from the chemical and health standpoint, the work of Dean and Arnold and Klein and many of them. There are numerous reports.

Dr. MILLER. Of course, some of those are just compiling reports from other scientists, is that not right?

Dr. BLAYNEY. No, I do not think it is just compiling of reports from other scientists. Their report is on their own original work.

As far as the American Dental Association is concerned, I am not aware of studies that they themselves have carried on. They have formed their opinions and based their recommendations upon the reports of others that are in the literature.

Dr. MILLER. That is all, thank you.

The CHAIRMAN. Dr. Hedrick, do you have any further questions?

Dr. HEDRICK. Doctor, is it true that Cleveland, Ohio, is about to enter into this program?

Dr. BLAYNEY. I understand it is.

Dr. HEDRICK. I heard that yesterday. Do you know of any other large city that is planning to use fluorination right away?

Dr. BLAYNEY. Chicago is holding hearings. They held a hearing yesterday for the proponents. The opponents are to have their day in court I believe some day next week, but I do not know when. I know that the city council has appointed a committee to study it.

Dr. MILLER. I have just one other question, Mr. Chairman, if I may.

The CHAIRMAN. Certainly.

Dr. MILLER. You see, I am sort of in between. I would like to recommend it, but it seems to me that there are so many unknown factors involved at the present time that more study is needed before we undertake this kind of a mass medication problem——

Dr. BLAYNEY. Sir, it is not medication.

Dr. MILLER. Well, what is it if it is not medication? It is a mass forcing of a chemical on everybody.

Dr. BLAYNEY. No, sir; it is not medication. This is my thought regarding that.

The body needs certain types of chemical elements to put it together and to let it rise to its full potential.

Now, maybe, with our civilization we have deteriorated and we have reduced the amount of certain elements that we should take in.

Fluorine is in many of our foods and maybe the fluorine content of these foods is getting lower than what it should be according to the general plan upon which the human was created.

Dr. MILLER. Yes, but, pursuing my question, is not medicine set up to prevent or cure or alleviate diseases?

Dr. BLAYNEY. No question about that.

Dr. MILLER. And fluorine is put into water to prevent caries. Well, what is the difference? It is a prevention program, it is a form of medication, it comes under medicine.

What is medicine if it is not dealing with the prevention and cure and amelioration of disease? I mean, when I vaccinate a kid against smallpox, I am giving him medication when I vaccinate him; and when you put fluorides in water you are preventing or hoping to prevent dental caries. So, it is medication and it is mass medication.

Dr. BLAYNEY. Well, if you had the right diet you would not have to give him, for example, ascorbic acid.

Dr. MILLER. On the other hand, you do not have to take ascorbic acid if you do not want to. My wife takes it every morning and I do not take it.

Dr. BLAYNEY. But you are treating the sick when you give the ascorbic acid. You are doing it if he does not have enough in his diet——

Dr. MILLER. Well, when you put fluorides in water, and we have to drink that water, it is mass medication.

Dr. BLAYNEY. Well, I cannot think of it in terms of medication.

Dr. MILLER. You cannot?

Dr. BLAYNEY. No, sir.

Dr. MILLER. That is all, Doctor, thank you.

The CHAIRMAN. If there are no other questions, we wish to thank you, Dr. Blayney.

Mr. KLEINFELD. The next witness is Dr. Hart.

The CHAIRMAN. Come forward, will you please, Doctor, and give your name and address to the reporter.

Dr. HART. E. B. Hart, Madison, Wis.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF E. B. HART, SC. D., PROFESSOR OF BIOCHEMISTRY, UNIVERSITY OF WISCONSIN, MADISON, WIS.

Mr. KLEINFELD. Dr. Hart, what degrees do you hold?

Dr. HART. Well, I was a student at the University of Michigan where I got a B. S. in chemistry in 1897. Then I studied in Europe, Marburg and Heidelberg universities, but I did not receive a degree there. The University of Wisconsin gave me the honorary degree of Sc. D., 3 years ago, 1949.

Mr. KLEINFELD. What have your special fields of professional interest been, Doctor?

Dr. HART. Nutrition, biochemistry.

Mr. KLEINFELD. Have you taught in any schools?

Dr. HART. The University of Wisconsin, since 1906.

Mr. KLEINFELD. For what period of time?

Dr. HART. From 1906 to 1945.

Mr. KLEINFELD. And were you a professor?

Dr. HART. Yes, professor of biochemistry.

Mr. KLEINFELD. What courses did you teach?

Dr. HART. Well, years ago I taught a course in agricultural chemistry. Then I taught a course in dairy chemistry and about 25 years ago began a course in nutrition.

Mr. KLEINFELD. Your special fields have been nutrition and biochemistry?

Dr. HART. Yes, sir.

Mr. KLEINFELD. Are you a professor emeritus?

Dr. HART. I am a professor emeritus; yes, sir.

Mr. KLEINFELD. In what field?

Dr. HART. Biochemistry.

Mr. KLEINFELD. Do you belong to any professional societies, sir?

Dr. HART. American Society of Biological Chemists; the American Chemical Society; the American Federation for Experimental Biology and many, more of which I have forgotten the names.

Mr. KLEINFELD. Have you contributed papers in your specialty to the professional publications?

Dr. HART. Yes; I think about 387, in my time.

Mr. KLEINFELD. Will you read your statement, please?

Dr. HART. I have the following statement on the fluorination of drinking water.

In 1946 there was definite agitation by certain dentists in Madison to add fluorine to our drinking water. Ours is a low fluorine water. The mayor of Madison appointed a committee and asked this committee for a recommendation to the city council as to what to do. This committee consisted of a bacteriologist, a chemical engineer, two biochemists, two nutritionists, two dentists, a pediatrician, a patholo-

gist, two doctors, and a layman. I was a member of that committee. After much study of existing knowledge the committee unanimously advised the mayor and the city council not to proceed with fluorination of our water. The committee did not deny that fluorine in proper concentration could be helpful in reducing the incidence of tooth decay.

However, they knew that there were several long-time experiments to be projected where communities of similar size would have available a fluorinated water and a nonfluorinated water. These were to be long-time experiments—10 years—with adequate dental and medical control. Newburgh and Kingston, N. Y., were chosen for the experiment. Other experiments were started at Grand Rapids, Mich., and Brantford, Ontario. Since these experiments were to be controlled adequately, the committee believed it prudent to wait until the 10-year data were in before deciding whether or not to fluorinate Madison drinking water.

However, enthusiastic dentists outside our committee prevailed upon the council to authorize fluorination, and so today that is what we have.

The data so far released from the Newburgh-Kingston experiment show about a 30-percent reduction in caries and that so far no pathological conditions have been reported. The report covers about 5 years of the 10. Those in charge insist that the experiment run for the planned 10 years before final recommendations are made.

It is with this point of view that I am in agreement; if after 10 years of careful control at Kingston and Newburgh the experts agree that fluorine in the amount of 1 part per million has had a definite influence in arresting a considerable percentage of caries and that no other untoward results are apparent, then and only then should the wide fluorination of low fluorine public drinking water be advocated.

However, it should be pointed out that there are communities in the United States that have drunk for years water with a fluorine content somewhat above the prescribed and advocated 1 part per million and without any definite recorded pathology except in some cases a slight mottling of the incisors.

Fluorine is an extremely toxic element but like copper and other nutrients there are levels that may be used safely. If in addition, fluorine has the added virtue of arresting in considerable degree the development of dental caries, then more power to it.

Dr. MILLER. May I interrupt?

Dr. HART. Yes, sir.

Dr. MILLER. You spoke about fluorine being an extremely toxic substance. Now, when fluorine is added to water when you are cooking beans and potatoes, for instance, and you are boiling off the water and putting in more and more water containing fluorine, does that fluorine boil off as a vapor or does it stay in that water and become more concentrated?

Dr. HART. It stays in as a salt.

Dr. MILLER. As a salt?

Dr. HART. As a salt, yes; like calcium fluoride or sodium fluoride. It would not be vaporized and go out.

Dr. MILLER. So, if you kept on adding more and more water you might get quite a bit of fluorides?

Dr. HART. Yes; you would be concentrating the fluorides in the residue water.

Dr. MILLER. I see.

Dr. HART. Unless the situation were acid so that you liberated the free hydrofluoric acid. It is as if you have sodium iodide which is a salt. If the conditions become acid so that you liberate the iodine as hydrogen iodide; the same thing happens with fluorine and those two elements can be vaporized or driven off by boiling—but not when they exist as salts.

Dr. MILLER. Yes, all right, thank you.

Dr. HART. But the level of safety must be established and that is just what the Kingston-Newburgh experiment is designed to do. After 10 years, or by 1955, we will have more definite information on which to make definite recommendations.

My own experience in feeding fluorine-carrying salts has been entirely with domestic animals, the cow, pig, chicken, and certain laboratory animals. From this work we have fixed the safe and tolerable level as follows:

For dairy cattle, 1 to 2 milligrams daily per kilo of body weight.
For swine, 5 milligrams daily per kilo of body weight.
For rats, 10 milligrams daily per kilo body weight.
For guinea pigs, 12 milligrams daily per kilo of body weight.
For chickens, 40 milligrams daily per kilo of body weight.

This work grew out of an attempt to find a cheap substitute for bone meal as a source of supplementary calcium and phosphorus in the ration of these animals. It was believed that rock phosphate could act as such a supplement. But this material carried 3.5 to 4 percent of fluorine and so it became necessary to determine the safe level at which fluorine could be ingested in the ration of our domestic animals.

The criteria used were growth, reproduction, and lactation in the case of the cow and pig; the condition of teeth was also studied. In the case of the chicken, growth and egg production were the criteria. The lowest level of fluorine fed the cows was 0.625 percent of rock phosphate in the grain mixture or 0.022 percent of fluorine in the grain mixture. At this supposedly low level of fluorine, toxicosis developed, but only after a considerable period of time—2 years. Excessive molar abrasion was apparent and growth as well as milk production was somewhat impaired. The level of 0.625 percent of rock phosphate was equivalent to about 1 to 3 milligrams of fluorine daily per kilo of live weight. This was too high. It meant an ingestion of 0.5 to 1.5 grams of fluorine per day for a thousand-pound cow. This would mean that a rock phosphate level in the grain mixture of 0.25 percent could probably be tolerated without physiological harm. However, we did not feed levels as low as this.

A water with 1 part per million means about 1 milligram of fluorine in a quart. For comparison purposes let us put this amount of fluorine on a milligram per kilo of body weight basis. A child weighing 10 kilos or 22 pounds would be ingesting daily with a quart of such water about 0.1 milligram of fluorine per kilo of body weight. This is well below what we found as the safe level for the cow, the most sensitive animal with which we worked.

I emphasize this experience with dairy cattle as illustrating the bad effects that may result from what we thought was a low fluorine intake, but fed over a long period of time.

The bones of the newborn animal are practically free or at least very low in fluorine content.

At this point I might comment on the preceding testimony with reference to Pablum. They were probably using some old bones rather than young calf bones, because had they used a young calf's bones they would not have had a high source of fluorine or a high fluorine content in the Pablum.

During the life of the animal the fluorine of the food and water is stored in the bones, but with partial elimination in the urine. If the fluorine level in the diet and water reaches a point where the capacity of the bones to store fluorine has been met, then there will be an overflow into the soft tissues. When this occurs the possibility of damage to the kidney, liver, and heart becomes real and interference with the function of the normal enzyme systems may result.

All this is why I prefer to wait until the completion of the Kingston-Newburgh experiment before recommending the general fluoridation of water for drinking purposes. Time of ingestion as well as level are important factors in this problem as it relates to dental caries in humans.

Quoting the report of the committee in charge of the interpretation of the data on the Newburgh-Kingston study, American Journal of Public Health, June 1950:

> These data are preliminary and it will be necessary to continue collecting data for the proposed duration of the study, that is through 1954 to 1956, to obtain additional information concerning the prophylactic value of fluorine.

Also—

> Final conclusions regarding the possible systematic effects of fluoride in the dosage employed should not be drawn before termination of the 10-year study.

Thank you.

I might add that the report I sent sent here—I sent three copies and if you will allow me, there is an additional statement that could be added which comes from a later progress report on the Newburgh-Kingston studies. In that report for February 1951, they state:

> "The D. M. F. rates among permanent teeth of 6- to 12-year-old children in Newburgh show a consistent downward trend after 4 years of fluoridation whereas D. M. F. rates in the control city of Kingston show no change."
>
> 1. 20.6 D. M. F. per 100 permanent teeth to 13.9 or a reduction of 32.5 percent in Newburgh.
>
> 20.2 D. M. F. per 100 permanent teeth remained the same in Kingston.
>
> 2. 6.7 deciduous cuspids per 100 in Kingston free from caries.
>
> 21.3 in Newburgh.
>
> These results over the period involved, namely 4 years, indicate a partial solution of the dental caries problem.

Dr. MILLER. Doctor, I just want to ask you one or two questions.

I take it from your testimony that you are not ready to say to this committee to go ahead and write a recommendation that it be used universally in drinking water.

Dr. HART. Why, I think it is always wise, when you plan an experiment and you have as good controls as the Newburgh-Kingston experiment, and where you have competent people to decide finally the values, that it is wise to wait for their decision.

Dr. MILLER. Do you agree with Newburgh-Kingston people that fluorine reduces caries when added to water?

Dr. HART. Well, of course, I would say that the evidence is that there is some help, but——

Dr. MILLER. Well, you said that fluorine as such is a poison, did you not?

Dr. HART. Fluorine is a toxic element. It is not known yet whether it is required, whether it is a necessary element in human and animal nutrition. That has never been adequately determined.

Dr. MILLER. Would you agree that medicine deals with the prevention and cure and relief of disease?

Dr. HART. Yes.

Dr. MILLER. And would you agree that the objective of putting fluorine in the water is to perhaps prevent or stop dental diseases?

Dr. HART. I think so.

Dr. MILLER. Or caries.

Dr. HART. I think so.

Dr. MILLER. Then in that instance that would really be a mass medication, would it not, in water?

Dr. HART. Yes. It is like the effort to have mass medication by the use of all salt being iodinated.

Dr. MILLER. Yes.

Dr. HART. And that Congress would not agree to.

Dr. MILLER. The other witness preceding you took some exception when I said it was mass medication, but it does seem to me that if you draw it down to its right conclusion and if medicine is the cure and amelioration and prevention of disease, then if you use fluorine to prevent or alleviate dental caries, then it is medicine, it is medication, just like putting iodine into salt.

Now, I am not saying I am opposed to it, I am trying to find out the facts because I still am not prepared to state whether I believe it is a good thing or not, I want to know more about it, all of us on this committee do. We on this committee will have to ask a lot of questions before we recommend and so I like to get someone like you on the spot to say "Yes" or "No" about recommending the universal application of fluoride in water. Then, we would have somebody to back us up.

Dr. HART. Well, I have made my statement here.

Dr. MILLER. All right, I will examine it carefully, and if I feel I am on a limb I will say, "All right, I will refer you to this professor from Wisconsin." You may hear from us. That is all.

Mr. KLEINFELD. Dr. Hart, on the first page of your statement you discuss the committee that was set up by the mayor of Madison in 1946 to decide what to do about the fluoridation of drinking water. In your statement you say that notwithstanding the adverse recommendations of the committee—

> enthusiastic dentists outside our committee prevailed upon the council to authorize fluoridation and so today that is what we have.

Can you tell the committee how it was that these enthusiastic dentists prevailed upon the council to do so, notwithstanding the advice of the committee that was set up to decide that very thing?

Dr. HART. I do not know their technique.

Mr. KLEINFELD. In that connection, Dr. Hart, what objections did your committee have in recommending against fluoridating the water supply of Madison?

Dr. HART. Well, as I said in my statement, the committee was familiar with the set-up of these long-time experiments; and that was a scientific method that had been put into effect; and the com-

mittee hesitated to make a recommendation until the end of that type of experiment.

Mr. KLEINFELD. Dr. Hart, I believe you point out on page 1 of your statement that there are a number of communities in the United States whose water naturally contains more than 1 part per million of fluorine, and that your committee had been told that no ill effects have been reported.

Now, is that not sufficient proof of the safety of adding fluorides such as sodium fluoride to the public drinking water in the amount of approximately 1 part per million?

Dr. HART. I know that such statements have been made but I wonder whether really there has been any accumulated evidence from expert examination to show that there were no untoward influences over the time. As a matter of fact, we simply do not know.

As I always emphasize, the toxic limit is a tremendously important matter and when we find communities ingesting a fluorine content such as indicated and nevertheless have gotten along well and apparently have had no recorded pathology, yet we wonder how well controlled was the examination and whether there is not something after all that did develop that we do not know anything about.

Mr. KLEINFELD. Do you know in what form the fluorine appears in the localities which have fluorine naturally present in their drinking water?

Dr. HART. No one knows. You see, we have many salts in the water and you have what the chemist calls double decomposition and equilibrium appears in one form for some and another form for another, depending on the surplus of one particular salt. There might be some calcium fluoride or some sodium fluoride of a silicofluoride, and so on. No one knows.

That is a great indoor sport, to take the total analysis of a water and then try to fix in what compound the fluorine existed. It never has been done and it never can be done.

Mr. KLEINFELD. If that is true, Doctor, I would like your opinion on this. Is it safe from the viewpoint of the conservative scientist to come to conclusions with respect to the addition of sodium fluoride to drinking water in complete reliance upon the apparent results or the vital statistics dealing with those localities which have fluorine naturally in their public drinking water?

Dr. HART. Well, it is the best information you have at the present time; but you must be conservative, you must admit that there are some loopholes, some things we do not know. But it is the best that you have and that is about all that you have.

Mr. KLEINFELD. Then as I understand your statement, Doctor, the control studies which are being carried on in cities like Newburgh and Kingston are designed to dispel those uncertainties?

Dr. HART. They should help. As an illustration, with some animals, for instance, you can get results in a short time. Now, man lives for a very long period in comparison. The question is, why were 10 years selected? Perhaps if they had selected 50 years they would give us better data at the end of 50 years than they will at the end of 10 years.

Mr. KLEINFELD. Your statement, Dr. Hart, deals with the controls exercised in cities like Newburgh, Grand Rapids, and Evanston. Are

you familiar with the type of medical controls exercised in these pilot cities?

Dr. HART. No; I am not.

Mr. KLEINFELD. From our examination, for example, of the reports of the Newburgh-Kingston experiments, it appears that only children are being medically examined. In your opinion, is it or is it not important to check other age groups, such as people who are in their fifties, sixties, or seventies?

Dr. HART. I think it is quite important to cover the whole field.

Mr. KLEINFELD. Well, if it is a fact and I think it is a fact, that in a city like Newburgh, for example, which was discussed in your statement, from a medical viewpoint only children are being examined, are you going to be satisfied with the results of those studies when they are completed?

Dr. HART. Well, the population may not be satisfied.

Mr. KLEINFELD. How about yourself?

Dr. HART. I would like to know more about the adults, too.

Mr. KLEINFELD. Would you be interested in knowing more about both the child and the adult and the aged who may have been suffering from kidney disorders?

Dr. HART. Yes; I would like to know about that, too.

Mr. KLEINFELD. Then, should these pilot cities, in your opinion, be studying those aspects of the problem, too?

Dr. HART. I think they should; yes.

For example, if I may go on; when we were working with our animals, we put their tissues through histological and enzymatic studies to determine whether there were influences, particularly on the enzyme systems, of certain levels of fluorine.

We concluded that fluorine is very reactive in certain enzyme systems and that the general reactions which we got with our animals were very much evidenced not merely in the teeth and bones but also the soft tissues. From studies with what we call balanced experimentation on income and outgo, it was very apparent that with our animals there was storage of fluorine.

That is, the amount of fluorine in the bones would rise in those that were getting fluorides, 15 or 20 times that which was in the bones of the animals which were not getting fluorides.

So long as there is that storage possibility and the bones can pick it up, and keep it from getting to too high a concentration in the soft tissue, then a measure of protection is available.

But if you overreach that point then disaster follows. It influences the enzyme systems.

We would like to know the effects in that regard fully. We will not know that, however, from the Newburgh-Kingston experiments; they will not be able to give us such data because they cannot sacrifice the individual and so we are not going to have as complete data as you and I might like to have.

As I said before it has never been established that fluorine is an essential element for the life of a mammal. Perfectly good teeth and bones are made without fluorine in the diet by getting the fluorine just as low as possible in the experimental diets.

Dr. MILLER. If I might ask the doctor a question at this point. Do you know what experiments are carried on by the United States Public Health or the American Medical Association or the Ameri-

can Dental Association that caused them to conclude that fluorine should be used more or less universally in drinking water?

Dr. HART. Well, individuals have published analyses of teeth and that sort of thing but I do not know of any mass studies they have carried on. They may have, but I do not know.

Mr. KLEINFELD. Do you know whether any experimental studies have been carried on either in the pilot cities or elsewhere to determine whether the addition of sodium fluoride in drinking water may add to the brittleness of the bones of people who are in the aged portion of our population?

Dr. HART. No, I do not know of such experiments. I do know of such experiments with animals.

We have carried on plenty of experiments where we had excessive amounts of fluoride in their diets, with a result that the bones become of increased size, their breaking strength being actually increased rather than lowered. But, at the same time, because of fusion at the joints of those bones, the animals would be unable to walk.

Of course, those were experiments where we used excessive amounts of fluorides.

Mr. KLEINFELD. How is fluorine excreted from the body?

Dr. HART. It is excreted in the urine, the larger amount of it. Of course, it divides itself. Some will go out in the feces, but it is usually in the urine, that will be the main excretory channel. It depends upon a lot of things in the diet. If you have an excess of calcium salts in the diet the fluorine is likely to go largely by way of the feces.

Mr. KLEINFELD. Might there therefore be a greater problem in the case of those people who have some kidney disorder?

Dr. HART. That I would not know.

Mr. KLEINFELD. Is it scientific, Dr. Hart, to say that because naturally fluoridated water has not been shown to cause harm to anyone, that is, the vital statistics do not show that specifically or because apparently there is no greater incidence of particular diseases in these localities, the addition of a fluorine compound like sodium fluoride in drinking water would have exactly the same biological effect?

Dr. HART. I do not know.

Mr. KLEINFELD. Do you know of anybody that has made any definite research or experimentation to try to determine that rather important fact?

Dr. HART. You mean, as to the form the fluorine takes when it is added to the water?

Mr. KLEINFELD. No. Let us assume that we want to add sodium fluoride to water which does not naturally contain fluorine. Do you think that we can rely entirely on the fact that, in a community the water of which contains natural fluorine, apparently there has not been any greater incidence of various diseases and people do not seem to be dying any younger than in any other localities? Is that a safe scientific conclusion to make?

Dr. HART. It would be difficult to answer that. We do know that there are differences in the effects of calcium fluoride as contrasted with sodium fluoride. One is a more soluable salt and we will get detrimental reactions at a lower concentration than in the case of a more insoluble salt.

Now, in the case of adding it to the water, what form it takes is going to depend on what the constituents of that water are.

So, you have all sorts of distributions among the various other salts that are in that water when you add the sodium fluoride.

Whether they are going to be different in effect is not known. For instance, in our State which has the record of having more fluorinated water than any other State in the Union—they are adding in one case hydrofluoric acid and more often it is sodium fluoride—no one can answer the point as to whether these different forms that might be used as carriers of the element fluorine, no one can answer that question as to whether they are going to have different physiological effects.

But we do know with our animal work that calcium fluoride because of lower solubility is less toxic at the same level of fluorine than sodium fluoride.

Mr. KLEINFELD. To carry that on a little further in a somewhat different direction, Doctor, we have had testimony that fluorine is present in certain foods.

Dr. HART. Yes.

Mr. KLEINFELD. Such as fish.

Dr. HART. Yes.

Mr. KLEINFELD. And some breakfast foods.

Dr. HART. Yes.

Mr. KLEINFELD. Is the solubility of the fluorine in those foods and the fluorine or the sodium fluoride in drinking water the same?

Dr. HART. No one knows. Well, drinking waters may vary as to the forms of fluoride they may have, depending on the salts that were there to meet it when you put it in.

Now, in the case of the fish, you have all sorts of organic compounds with which the fluorine can unite. So you will have different forms of organic fluorine compounds. You may have a protein, possibly, combined with the fluorine, or you may have fats combining with the fluorine, just as you may have iodine combining, for instance, with the fats or protein of linseed oil meal. In that form it is much more stable than when you have a potassium iodide. There are all sorts of combinations and nobody knows what they are.

Mr. KLEINFELD. Well, is this solubility an important thing to be considered in connection with the fluoridation of water?

Dr. HART. I know that was raised in our committee at the time we gave our report to the Mayor, as to what the effects were on solubility. Nobody can answer that.

Mr. KLEINFELD. I have no further questions.

Dr. HEDRICK. Doctor, these animals to which you fed large quantities of fluorine, did you say that you made some histological slides on those animals?

Dr. HART. Yes.

Dr. HEDRICK. Did you find any change in the kidneys?

Dr. HART. Yes, there were necrotic areas in the kidney.

Dr. HEDRICK. You did not find any kidney stones?

Dr. HART. No; we did not find any kidney stones; no, sir.

Dr. HEDRICK. Or any deposit of crystals in the tissues?

Dr. HART. No.

Dr. HEDRICK. Do you think that there is any possibility that there may be a connection between fluorine and hypotrophic arthritis?

Dr. HART. I do not know.

Dr. HEDRICK. That is a condition where there is an increase in bone tissues around the joints; where there is an increase in bone deposits?

Dr. HART. Of course, when excessive amounts of fluorine were used, we saw that in our animals. I wish I could have brought with me bones from these animals that had excessive amounts of fluorine, and also their teeth.

Now, you know, there is no explanation at the present time as to how fluorine helps the tooth to prevent caries; it is a fact, that if you feed high levels of fluorine, going beyond the point of having mottled teeth, that tooth becomes soft, not hard. It becomes soft.

Our cattle with excessive amounts of fluorine showed great abrasions of their teeth. They failed to drink cold water and we wondered why and when we opened their mouths and examined them, we found that their teeth were greatly abraded, right down to the pulp cavity; that was open, and the food was getting into the pulp cavity and there was putrefaction and pain. An excessive amount of fluorine gives soft teeth.

Now, there is no sound evidence as to how fluorine acts, to make a hard tooth with the smaller quantities.

Of course, on the blackboard I can write a formula for you as to the possibility of small amounts of fluorine, say, displacing an hydroxyl group in the complex calcium phosphate or carbonate hydroxide structures of the tooth, but nobody has given us evidence that that is what it actually does.

Dr. HEDRICK. Well, an excessive amount of fluorine in drinking water would be very dangerous for a community, would it not?

Dr. HART. Well, I would not say that, from the evidence that is accumulating in Newburgh at the present time and at Kingston and other places.

Dr. HEDRICK. Well, you say it might cause a softening of the teeth——

Dr. HART. At higher levels.

Dr. HEDRICK. That is what I mean, an excessive amount of it.

Dr. HART. Yes, with higher levels; at least, it did with our animals.

Dr. HEDRICK. Certainly it would do the same thing in humans, I would think.

Dr. HART. Could be.

Dr. HEDRICK. Do you know of any green garden vegetables that have any fluorine in them?

Dr. HART. All of our plants have. Now, that problem worried us a good deal 15 years ago.

That is because in agriculture we had been fertilizing our fields with rock phosphate and rock phosphate is a carrier to the extent of 3½ to 4 percent of fluorine, and when you make acid phosphate from rock phosphate, you leave half of the fluorine in the acid phosphate and that goes onto our fields.

We were worried whether we were not running into a very important problem, by adding about 35 pounds of fluorine to every acre of soil every time we put on 1,000 pounds of rock phosphate, and we wondered where it was going and what was happening.

So, we went to Pennsylvania Agricultural College where they had some very old experiments and to Illinois and to Ohio experimental stations, too, where they also had some very old experiments, where they had been fertilizing plots of grains and grasses with bone meal

which is relatively low in fluorine and with rock phosphate, which is high.

We took those plants, some wheat, some corn, and some alfalfa, and so on and began analyses for fluorine to see whether we were going in the wrong direction in our fertilizing program in agriculture.

But, the evidence showed that those plants were not picking up more fluorine from the soil where high fluorine had been added.

So then, we went down to Tennessee, where they had lysimeters. Now, a lysimeter is a block of ground left intact and underneath dug out and where you can have receptacles to catch the rain water as it comes through the surface soil. These surface soils were fertilized in different ways, high and low fluorine.

We found that the fluorine from the rock phosphate or the acid phosphate additions, was going into the drainage waters and ultimately it was going to get into the drainage systems of the land. However, the plants themselves, the seeds especially, showed no increase in fluorine content over the controls.

Dr. HEDRICK. Is that true of celery and produce like that?

Dr. HART. You would expect the leafy parts of plants to pick up a little more, but there was nothing striking, although you should remember that we are getting fluorine all the time in our food in certain amounts—luckily, it is small.

Dr. HEDRICK. There is probably more fluorine in seafood than anything else.

Dr. HART. Yes, that is true.

Dr. HEDRICK. Perhaps we are getting enough without adding it to our water. What do you think about that?

Dr. HART. Well, it does not seem to prevent caries; and the addition, if these experiments are correct, indicate that one can help that way in the reduction of caries, with this level of one part per million in the drinking water.

I had a very interesting letter, if you will allow me to comment. Will you?

Dr. HEDRICK. Yes, if it is all right with the chairman.

The CHAIRMAN. Yes.

Dr. HART. I had a very interesting letter from a doctor the other day in which he thought we were on the wrong track in adding flourine in water because of the varying amounts we consume or the children consume.

When the child is a baby, he drinks milk. They do not drink much water, they drink milk.

There is very little fluorine, if any, in milk, practically none. Now, he wanted to know why should we not add fluorine to our milk. And he wanted to know, should we not add it to the cows' ration so that it would go over into the milk.

Well, we happen to have had experiments on the subject and we knew that you do not transmit fluorine through the cow into the milk from the feed.

He told how he had added fluorine to the milk of his own children and the excellent teeth that they had. That was from his own personal experience, by adding it to milk rather than adding it to water.

Dr. HEDRICK. Thank you.

Mr. KLEINFELD. If adding sodium fluoride to milk were effective then those people who wanted fluorine could get it in the milk and those who did not want it could avoid it.

Dr. HART. Yes.

The CHAIRMAN. Thank you, Doctor.

There is just one thing I was thinking about. I do not know whether you are qualified to answer it.

You talked about the solubility of fluorides, particularly calcium fluoride. Now, how soluble is this fluoride that is added to the water?

Dr. HART. Well, it is in solution apparently; it is in what we call a solution.

The CHAIRMAN. Well, if we take a gallon of it, let us say, and put it in a reservoir, how are we going to be assured that that is evenly distributed throughout all of the water. What is the physical method of doing that, if you know?

Dr. HART. I do not know, but I understand the engineers have worked out efficient ways of adding fluorides to water.

The CHAIRMAN. So that it is equally distributed and so that no greater quantity would be in one portion of the water than in the other?

Dr. HART. That is what the engineers say. I do not know.

The CHAIRMAN. Of course, we can realize what might happen, especially from your testimony, if it were not evenly distributed and there was too much in a portion of the water. Thank you, Doctor.

Mr. Kleinfeld, will you call the next witness?

Mr. KLEINFELD. Dr. Hurme.

The CHAIRMAN. Will you give your name and address to the reporter?

Dr. HURME. Veikko Oscar Hurme; 140 The Fenway, Boston, Mass.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF VEIKKO OSCAR HURME, D. D. S., DIRECTOR OF CLINICAL RESEARCH, FORSYTH DENTAL INFIRMARY FOR CHILDREN, BOSTON, MASS.

Mr. KLEINFELD. Dr. Hurme, what is your academic background?

Dr. HURME. Before entering dental school, I spent 3 years in the School of Liberal Arts at Tufts College and then I graduated from the dental school in 1934, cum laude.

Mr. KLEINFELD. What school?

Dr. HURME. The same college.

Mr. KLEINFELD. Tufts?

Dr. HURME. Tufts.

Mr. KLEINFELD. What has your professional career consisted of since you graduated?

Dr. HURME. Well, immediately upon graduation I was asked to join the teaching staff as instructor in operative dentistry.

Mr. KLEINFELD. At Tufts?

Dr. HURME. At Tufts.

Mr. KLEINFELD. How long were you connected with that college?

Dr. HURME. I was connected in that capacity from 1934 to 1938 and again from 1940 to 1941. The period from 1938 to 1940 I spent

at Yale University Medical School and as a resident intern at the New Haven Hospital in New Haven, Conn.

Mr. KLEINFELD. Are you a member of any professional societies?

Dr. HURME. I am a member of several societies, including the International Association for Dental Research, Sigma Chi, American Association for the Advancement of Science, American Association for Physical Anthropology, the Society for Research in Child Development. Those are the chief ones.

Mr. KLEINFELD. Have you contributed papers to the profession in the field of dentistry?

Dr. HURME. I have contributed approximately a score of papers since 1934.

Mr. KLEINFELD. What have you been doing since 1941?

Dr. HURME. Since 1941 I was at the University of Illinois as assistant professor in operative dentistry.

Mr. KLEINFELD. And subsequently?

Dr. HURME. In 1946 I came to Boston to join the Forsyth Dental Infirmary for Children as director of clinical research.

Mr. KLEINFELD. You hold that position now?

Dr. HURME. I do.

Mr. KLEINFELD. What is the Forsyth Dental Infirmary for Children?

Dr. HURME. It is an endowed institution which started operating around 1915, and it is devoted to providing dental service for children. It is chartered to carry out such studies as are possible to find out what the problems of dental disease are; in other words, to do some research.

Mr. KLEINFELD. Does it have both a dental and medical department?

Dr. HURME. We have on the staff a medical man. It is not a big department, but we do have one physician.

Mr. KLEINFELD. You have a research department?

Dr. HURME. Well, research more or less permeates the whole building. In other words, very many of the children who come in to us are being studied with research in mind.

Mr. KLEINFELD. About how many children do you treat over the course of a year?

Dr. HURME. You embarrass me now. It is a very large number.

Mr. KLEINFELD. Approximately, I mean.

Dr. HURME. There are several hundred children treated annually.

Mr. KLEINFELD. Will you proceed with your statement?

Dr. HURME. This statement, dealing with the need for an impartial scientific reevaluation of proposals to add inorganic fluorides to public water supplies, has been prepared at the request of the Select Committee to Investigate the Use of Chemicals in Food Products of the United States House of Representatives for presentation before the committee on February 21, 1952. It consists of the major portion of an unpublished paper entitled "An Examination of the Scientific Basis for Fluoridating Populations," pages 2, 3, and 4 of which have been omitted as irrelevant.

INTRODUCTION

The discovery that fluorides may be of value in reducing the prevalence and extent of dental decay is a contribution of major importance in the field of dentistry. It is only proper that much credit should be

given to the men who have worked for years to make this theoretically valuable contribution, and who have provided scientists with a concrete starting point from which it may be easier to push further into the mysteries that still surround the causation and prevention of dental disease.

The proposals to raise artificially, to predetermined levels, the fluorine concentrations of all public water supplies which may be judged to be "deficient" in the concentration of this element, stem from a concept according to which there is an inverse relationship between the fluorine content of a tooth and its susceptibility to decay. Since the fluorine content of a tooth appears to depend primarily upon the quantity of fluorides taken into the body during the period of tooth development, the advocates of universal fluoridation believe that the best practical means for insuring a sufficiently high fluorine content of teeth is by compelling all children in a community to ingest fluoride-bearing water. The fact that such a method necessitates the consumption of fluoridated water by all segments of a population is not looked upon by the proponents of mass fluoridation as of sufficient import to interfere with the immediate acceptance of the prophylactic technique they favor.

CONTROVERSIAL POINTS

1. Nutrition: Fluorine never has been proved to be an indispensable chemical element for the maintenance of healthy body or healthy teeth. So far as available scientific evidence goes, life can be maintained without the presence of fluorine compounds in the body. In this respect it is comparable to radium, of which normal human tissue is reported to contain on an average 186 atoms per cell. Although radium possesses incredibly potent physiological action, there is no evidence whatever of its indispensability for the functioning of a normal healthy living cell. If the body can tolerate minute quantities of certain "trace" elements like radium or fluorine, are we not on unsafe ground when we infer that such unavoidable contaminants are essential for life and health?

There has been more and more tendency to designate fluorine as a dietary essential, although it is clear that this argument cannot be upheld until the physiologic indispensability of fluorine has been definitely established. It is quite clear, however, that the problem of fluorine intake and elimination must be studied against a background of the general dietary and nutritional status of the individual. The presence of other minerals in the diet, such as calcium and magnesium, has an effect on the action of fluorine. Furthermore, since very little is known about fluorine in various organic combinations, in contrast to more extensive information about inorganic fluorides, it appears presumptuous today to claim that inorganic fluorine added to drinking water is the precise equivalent of similar concentrations of naturally occurring fluorine compounds in water and foods.

The claim made by some water engineers that the water in the distribution system has no "demand" for fluorine—as it has for chlorine—suggests that fluoridated water is inferior to purer water for the maintenance of life. The minute organisms present in water do not consume fluorine. A similar biologic assay is furnished by insects that prefer unprocessed flour to processed flour.

In the light of present-day information, one may hypothetize that if an organism needs a trace quantity of fluorine as it needs a trace quantity of cobalt, this trace quantity is generally available all over the earth, without recourse to artificial supplementation. Some of the highest life expectancies are reported from the regions of the globe with the least fluorine in soil or water.

Although water is not ordinarily classified as a food, everyone knows that without water nutrition is an impossibility. Man can get along without many specific compounds designated as foods, but he cannot live without water. Therefore, if great pains are taken by the United States Food and Drug Administration to insure a high quality of foods, drugs, and cosmetics, even greater pains should be taken to insure the highest quality of public water supplies.

Rather marked indivldual variations in the consumption of water and food preparations complicate the problem very much. These variations, in turn, are tied up with such special aspects of the main problem as inherent biologic variation and physiologic food and water requirements in health and disease.

2. Toxicology: The uncertainty that exists in the minds of many regarding the advisability of adding fluorine compounds to any public water supplies is due, primarily, to the very incomplete state of our knowledge about the toxic effects of fluorine in its various forms. There is no disagreement about the fact that fluorine is a protoplasmic and enzymatic poison. Controversy arises only when those, who are in favor of treating everyone in a community with fluorine, state that there is no need for concern over the toxicity of minute quantities of this element over a life span of time.

Many contradictory and unwarranted assumptions and diversionary issues have beclouded the main problem. For this reason it is now impossible to deal with the toxicology of fluorine both briefly and comprehensively. It appears better to attempt a review of the present state of knowledge by examining the various special aspects of the problem separately, under appropriate subject headings.

3. Biologic variation: Although the universality of biologic variation has been recognized for a long time, the import of this phenomenon does not appear to be fully realized by all men in various branches of applied biologic science. This is true, to a fair degree, of such applied sciences as medicine and dentistry, with which we are now concerned.

Variations in anatomical form, biochemical constitution, physiological function, et cetera, frequently lead to variations in the adaptability of man to his environment. If his biological reactivity is adequate to protect him from the normal environmental hazards of life, he is healthy. Disease, or malfunction, or death occur when certain personal deviations are so great that compensatory or adaptive processes temporarily or permanently fail to make the person adequately responsive.

It would seem that all arguments for recommending impregnating every person in a community with a daily dose of fluoride are bound to be seriously defective arguments until we possess well-documented scientific evidence on the phenomenon of human variability in regard to fluoride tolerance. The problem is of prime importance for a number of reasons.

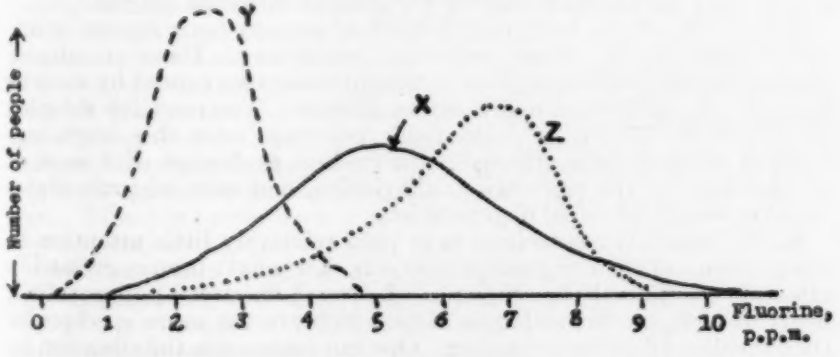
The most important single reason is furnished by the numerical size of the population groups to be treated with fluoride. Since no one to date has suggested the installation of duplex types of public water systems—one set of water mains for pure water and a second set for fluoridated water—it is obvious that, for all practical purposes, approval of fluoridation will make fluoridation compulsory for every individual living in a community. Every human body is to be treated with the chemical; the unborn, the young, the middle-aged and the old; the sick and the well; those with teeth and those without teeth; those who believe in medication and those who do not. The procedure will be mass medication of truly heterogeneous population groups, without parallel in the annals of medicine.

Available scientific data, including dental statistics, provide ample support for the argument that the ranges of inherent biologic variation in fluoride tolerance are very large for many species, including man. A statistician knows that, in trying to express variability mathematically, he is on proportionately safer ground the larger is the so-called "random sample" on which he bases his computations. Not only does he desire as large a sample as possible, but he also wants to be certain of a high degree of "randomness," or representativeness in his sample. On the basis of vast experience scientists know that the upper and lower limits of variation generally are the farther apart the larger, numerically, is the group under study.

Universal and constant utilization of fluoridated water naturally raises the question whether enough is known about biologic variation in fluoride tolerance for us to say that the chemical, in the concentrations proposed, does only good and never any harm. Are the safety zones so wide for one hundred thousand people, or for a million people, that the possibility of a health hazard remains purely theoretical and of no practical significance?

It can be said, without fear of contradiction, that the answer to the question just asked is not known. No medical statistician today knows how to draw a frequency distribution curve depicting fluoride tolerance, wherein the ordinates represent proportional numbers of people and the abscissae the fluoride concentrations that are the upper limits of safety for various sections of a population.

(Figure 1 submitted by Dr. Hurme is as follows:)



Dr. HURME. To elucidate this problem further, one might draw a diagram (fig. 1) that shows three hypothetical frequency distribution curves of fluoride tolerance. Curve X is a typical symmetrical

"normal" distribution curve with a wide base extending from about 1 part per million to almost 11 parts per million (hypothetical extremes of tolerance) and a summit at 5 parts per million (the average for the population). Curve Y is a much more "peaked" curve, with a summit at 2.5 parts per million and a narrower base between 0.25 part per million and 5.25 parts per million. Curve Z is a markedly "skewed" curve, rising gently from 1.75 parts per million to 7 parts per million and then descending abruptly to 9 parts per million. Any one of these three arbitrary curves may furnish the correct statistical description of fluoride tolerance in a large population. Yet they are all quite different from each other, indicating greatly different responses to fluoridation of masses of people. Actually, since we have no scientifically secure basis for fluoridation, it is possible that all three curves, X, Y, and Z, are wrong. The high tolerances shown are also likely to be a false representation of actual facts.

The most important part of any such frequency distribution curve is, of course, the left-hand portion, which shows the proportion of population subject to injury from low concentrations of fluorine. Unfortunately, the end portions of such curves can be determined accurately only by studying large population groups.

4. Medical studies: Among the causes of variation in fluoride tolerance variations in health, or physiologic efficiency, would seem to rank quite high. This theoretical aspect of the problem throws a great deal of responsibility upon such medical organizations as are asked to endorse the concept of mass fluoridation on the basis of existing scientific evidence. The very fact that fluorides are claimed, by many, to be potentially dangerous therapeutic agents, should be enough to motivate thorough investigation of the validity of these claims. Moreover, it can be pointed out that there is already considerable, more or less fragmentary, information in the literature which suggests the need for caution.

It is a fact, nevertheless, that medical literature today is peculiarly devoid of first-hand reports on the physiology of fluorine compounds. A perusal through the indexes of various medical journals quickly confirms this statement. In many seemingly exceptional instances further study reveals the references to fluorine to consist of abstracts of reports published originally in some nonmedical journal and written by some investigator outside the field of medicine proper.

The ability of the body to rid itself of various toxic agents is impaired markedly in certain pathologic conditions. There are almost no data today on the reductions in fluoride tolerance caused by various physical anomalies and degenerative diseases. The need for detailed studies of the elderly is particularly pressing, since this large segment of our population furnishes the medical profession with most of its problems in the prevention, alleviation, and cure of toxic states associated with physical degeneration.

So far, medical researchers have paid relatively little attention to the problems of chronic fluorine toxicosis. They have been engrossed in attempts to unravel the etiologies of several diseases—poliomyelitis, heart disease, cancer, arthritis, etc.—which are far more spectacular than insidious fluorine poisoning. One can summarize the situation by asserting that medical approval of fluoridation, based on thorough long-term investigations, is still needed.

It is known that the commonly employed medical diagnostic labels seldom give any definite indication of the etiologic factors responsible for the development of disease in any given instance. With the doubtful exception of some so-called infectious diseases, very few diagnoses are specific in an absolute sense.

The often repeated claim, that no harmful results have been noted from the ingestion of water containing only 1 part per million of fluoride, loses much of its force if the aforementioned point is kept in mind. The claim of noninjuriousness rests on a rather bold assumption, according to which signs and symptoms of fluorine poisoning are always sufficiently clear-cut to be easily recognized. This assumption has not been confirmed by positive evidence. Thus it follows that reliance on negative proof of fluorine toxication may be misleading. Positive evidence to corroborate the negative evidence is lacking.

A homely illustration may be helpful for conveying the intent of the preceding paragraph. If a stranger is admitted into a house because he comes to the door and claims that he has no money to pay for lodging at a hotel, he is admitted as a guest on the basis of good faith, or negative evidence. If his clothing and general appearance attest to the truthfulness of his claim, he may be admitted as a guest on the basis of implicit trust. However, only by subjecting the stranger to a thorough search of his body and of all his personal belongings can one obtain positive evidence of the truthfulness of his claim.

The need for epidemiologic surveys of fluorosis has been recognized recently. But in view of the uncertainty which exists regarding the signs and symptoms of subclinical fluoride poisoning, there is reason to believe that such surveys, although very desirable, will be of distinctly limited usefulness.

If the ingestion of fluorides over long periods of time should result in a shortening of some life spans by only a few weeks, or even a few months, such effects would not necessarily be obvious enough to be revealed by a cursory inspection of mortality statistics anywhere. A clue to such possibilities can be obtained best through experimentation with some species of mammals approximately as sensitive to fluorine as man. The possibility of shortening some life spans by even a month or two should be considered, and the difficulties of proper investigation should be disregarded, since huge sums of money are being spent annually for the express purpose of extending some life spans not more than a month or two.

5. Subjective signs, or symptoms, of fluorine toxicosis: It is well known that prolonged ingestion of minute doses of various toxic agents may not be associated with any definite subjective signs of danger. As regards fluorides, it is more than likely that we are dealing with chemicals that have particularly good desensitizing properties. Fluoride pastes have been used by many dentists for desensitizing hypersensitive dentin; they work very well in many instances, though not in all. Certain organic fluorides have become potent tools for the physiologist who is investigating the mechanism of transmission of nerve impulses, as it has been shown that they may inhibit the enzyme cholinesterase in nerve tissue.

There is considerable evidence according to which a high percentage of the fluoride absorbed through the intestinal tract rapidly finds its

way into various body fluids. Inasmuch as some 90 percent of the human body is water, there is no firm basis today for the argument that ingested fluorides cannot have the remotest influence upon the functioning of tissues other than bones and teeth. The gray matter of the brain is over 85 percent water. Since nerve function is not completely independent of the influence of calcium exchange and since the intake of fluorine, in turn, has some influence upon the utilization of calcium, it would seem that there is a good theoretical basis for insisting upon some study of the role of fluorides from the neurologist's viewpoint. As yet we are not in a good position to state categorically that the failure to associate any unpleasant nervous symptoms with the daily ingestion of small quantities of fluoride is a reliable criterion, indicating freedom from danger.

In the name of scientific impartiality it is only fair to point out that some dulling or retardation of nerve activity may be quite desirable in many instances. Some clinical observations suggest a close connection between a patient's neurologic status and the health of his dental organs.

6. Objective physical signs of fluorine toxicosis. A clarification of the problem of physical signs of fluorine toxicosis still is needed. Three explanations can be found for the incomplete state of our knowledge regarding this very important subdivision of the main problem: (1) the general, and probably universal, absence of diagnostic subjective symptoms in all cases of mild chronic fluorine toxicosis: (2) the diversion of attention by too much emphasis on the subjects of acute fluorine poisoning and the spectacular results of severe chronic fluorosis in its terminal stages; and (3) overmuch reliance on the assumption that only statistics on tooth enamel and studies of some physical properties of bones are needed for establishing the safety limits for ingestion of fluorides.

The last-mentioned point requires special elaboration. Teeth do no serve as useful toxicologic indicators for all, or even most, toxic substances. The vast majority of poisons produce no clinically detectable dental changes. Even if, for the sake of argument, we were satisfied with the proposition that in the case of fluorine we are dealing with an exception to the general rule, further reflection would readily disclose its limited applicability. The diffuse abnormal opaqueness of dental enamel, commonly referred to as mottling, is conceded to be due, in many instances, to excessive ingestion of fluorides during the period of enamel formation. Once enamel formation is completed, the intake of fluorides has little or no visible effect on normal enamel. Thus it follows that when the crowns of the third molars are fully calcified, the visible parts of the teeth cease to serve as indicators of excessive fluoride intake.

Among the very inadequately studied physical signs of fluorine toxicosis are inflammation and destruction of gingival and peridental tissue. Published and unpublished observations by many men suggest rather strongly that periodontoclasia, that is "pyorrhea," may be induced, or aggravated, by certain chemicals, including fluorides. Since the term "good dental health" denotes a satisfactory status of the teeth as well as of their supporting tissues, it is obvious why overmuch reliance on statistics which deal only with tooth enamel leaves much room for dissatisfaction.

It would lengthen this discussion unduly to review in detail all the information now available which indicates the reality of the need for knowing more precisely what may be the physical signs of fluorine toxicosis. One more insufficiently corroborated dental observation should be mentioned, nevertheless. There are some grounds for the belief that ingestion of fluorides may slightly retard the eruption of teeth. If this is a correct observation, it is evidence of a general physiologic response to fluoride consumption.

7. Dental statistics. Presently available statistical evidence, some of which is frequently quoted to prove the alleged benefits of fluoridation, suffers from a number of serious weaknesses.

The incompleteness of data on teeth has been mentioned already. As long as careful observation and statistical recording of data on the periodontal tissues are left out of the picture, only one-half of the story is being told.

The existence of considerable conflicting evidence in the published statistics dealing with fluoride concentrations and decay of teeth has been given rather scant attention. Equally disharmonious data on mottling and fluorine suggest the need for recognizing the problem as a multifactorial one, which cannot be settled by computing correlation coefficients for only two variables. Geographic, dietary, ethnic, and other factors loom significant in many instances.

The quality of the raw data on which the published statistical reports depend is, in many instances, open to question. Statistical generalizations are never better than the seemingly little individual units upon which they are based. The procedures of examining teeth are very difficult to standardize and the influence of personal bias on the part of examiners equally difficult to eliminate.

Those who are familiar with the details of studies involving observations on teeth know very well the difficulties inherent in all techniques devised for expressing dental decay numerically. The most popular technique—the DMF index—is ill-suited for scientific work involving the dentitions of children, especially those where a part of the deciduous dentition has been lost and only a part of the permanent one has emerged. The difficulties in this area are of a sufficiently fundamental character to justify a word of caution. Dental statistics today do not merit implicit trust, for purely technical reasons. The writer believes that he has had enough personal experience in this field to be aware of some of the pitfalls in the compilation and interpretation of dental statistics.

On the analytical level the situation is not any better. The procedures generally employed are such that all pertinent facts are not brought to light. It is, for instance, impossible to find out to exactly how many people the statistical generalizations apply. The basic data on teeth are not analyzed in such manner that one can say, definitively, first, what proportion of individuals appear to have benefited from the ingestion of fluorides; second, what proportion was not affected in any observable manner; and, third, what proportion may have been affected in an adverse, or injurious, manner. Even though the teeth of 99 people out of 100 might derive some benefit from fluoridation, it is important to know whether teeth of the hundredth person might show intensification of decay because of the treatment.

The method of computing the reductions in dental caries preva-

lence is also open to question. A few students of this problem have shown, rather clearly, I would say, that the commonly employed method of computation gives percentage reduction figures that are much too high and, therefore, misleading. The deceptiveness of certain statistical manipulations has been underscored in critical appraisals of the effectiveness of topical fluoride applications.

The value of published data on mottling of teeth is also debatable. This is due to the fact that a reconsideration of the classification of opaque enamel hypoplasias is needed before the problem can be studied statistically. The writer has contributed one report on this special subject.

8. Animal experimentation: Leading scientists in physiology, biochemistry, medicine, and pharmacology have recognized for a long time that science does not yet possess sufficiently delicate analytical technics to detect, with certainty, what is called subclinical injury. Usually there must be a great deal of damage to some organs of the body before we are aware of something being wrong.

In order to get clues regarding the toxicity of a chemical, tests on animals are utilized, and the greater the number of species available for such tests, the better. Besides various tests for acute toxic effects, or minimal lethal dose, long-term studies with small dosages are made. Large numbers of animals are studied and an effort is made to determine whether chronic toxicosis will lead to a shortening of the life spans of any in the group. The effect of antecedent or concurrent disease may also be taken into account in these studies.

Since the big problem in fluoridation is the ruling out of subclinical injury, or the existence of a health hazard to persons who are not completely healthy one is entitled to ask about the quantity and quality of animal experimentation that has been done in relation to fluoride consumption. Furthermore, since it is claimed that fluorine benefits the infant and child more than the adult, one has a right to ask how intensively the relationship between growth and fluorine ingestion has been investigated.

It is a surprise to find prominent—very prominent—gaps in this area of investigative science. Apparently animal experimentation has not placed us in a strong position for recommending immediate adoption of universal fluoridation where the natural fluoride content of water supplies is low. Most of the animal studies reported in the literature deal with the rat, or some other rodent, although it is known that the rat is far less sensitive to fluorine than man, in addition to being dissimilar in many other respects. The rodents, for example, never have two sets of teeth like man. It need hardly be pointed out that if no laboratory animals can be found exceeding man in sensitiveness to fluorine, then the results of even the best organized animal studies will have to be interpreted with considerable caution.

9. Biochemical studies: Biochemical technics appear to require much further development before we can secure authoritative date on the physiologic behavior of fluorides. The measurement of fluoride concentrations in the blood, for example, has not been satisfactorily solved.

10. Survey of literature: The world literature dealing with various aspects of fluorine intoxication, and so forth, contains many individual items (ranging from brief abstracts and incidental references in articles devoted to subjects other than fluorosis to extensive, book-length

monographs), the contents of which do not appear to be well known to all students of the problem. Relatively few institutions possess excellent collections of reprints and books on the subject. No one to my knowledge has prepared either an index on the basis of special subdivisions of the subject, or attempted a thoroughgoing, well organized review of the existing information. For this reason appraisal of the adequacy of published scientific data and of the theorization based upon it has not been at all satisfactory. The scientific basis for fluoridation will remain weak until all information now available has been subjected to rigorous critical evaluation, after painstaking summarization.

11. Mass medication: The proponents of fluoridation have been averse to the use of the term "mass medication." Instead, they have referred to it as a "preventive procedure," a "public health measure," or the like, which is similar to chlorination of public water supplies.

The dislike for the term "mass medication" is difficult to explain, inasmuch as it very accurately describes the concept underlying fluoridation. "Medicine," it is agreed, deals with the prevention, cure, or alleviation of disease. Prevention, or alleviation, of dental disease is the aim of treatment with fluorides. Vaccination, which is the medical procedure most akin to fluoridation, is for the purpose of preventing smallpox, rather than for the treatment of persons ill with the disease. It consists of introducing into the body a preparation which enables the body to develop immunity to a specific disease agent—the virus of smallpox.

Addition of fluorides to drinking water is not for the purpose of protecting the public against any water-borne agent or agents responsible for decay of teeth. There is no similarity here between chlorination and fluoridation. Chemically pure fluorides are drugs that are too poisonous to be dispensed to the general public over a drugstore counter, at least without a prescription. Even dental hygienists have not been permitted to apply fluorides topically, without amendment of the dental laws of the States.

Since "medication" refers to impregnation with anything medicinal, or with a drug or chemical, and since fluoridation is for the purpose of impregnating the public itself with fluorides, it appears pointless to confuse the issue by denying that this novel prophylactic procedure is a form of mass medicine.

CONCLUSIONS

The possibility of using fluorides for partial control of dental decay is an attractive one and certainly warrants additional study. As yet there is not enough scientific basis for recommending immediate acceptance of proposals to treat entire populations with fluorides. Available evidence does not permit one to take a definite stand in favor of daily fluoridation of populations any more than it gives one a right to take a definite, finalistic stand against the idea.

About all that can be said today is that mass medication with fluorides still is in the experimental category and that the need for broadening the scientific basis of the concept is quite real. Many preliminary precautionary measures should be taken in the best interests of the dental profession itself.

The design of the original mass fluoridation projects, which were set up with frankly experimental intent—and which, incidentally,

are not yet completed—is not comprehensive enough to answer all the important questions that must be answered before fluoridation can be considered out of the experimental category. Fortunately the problem of caries control is not of such urgency as to justify loosely controlled pharmaceutical experimentation on an unlimited scale today.

Each community that wishes to experiment with fluoridation should set up a local control study of its own. The proposals made today contain no recommendations to this effect, with the result that in the future we will not be any wiser than we are today regarding the advantages and disadvantages of mass medication with diluted poisonous chemicals. W. I. B. Beveridge, in his recently published book entitled "The Art of Scientific Investigation," calls the reader's attention to a pertinent observation made by Professor Wilson in England. I quote Beveridge:

> Unless decisive experiments are done before an alleged remedy is released for use in human medicine, it is almost impossible subsequently to organize an experiment with untreated controls, and so the alleged remedy becomes adopted as a general practice without anyone knowing if it is really of any use at all.

This very thing can happen with the use of fluorides, unless we watch out.

The exact role that fluorides may play in modifying the physiologic mechanism of caries production is quite unknown at present. Unless the physiologic indispensability of fluorine can be demonstrated, we must infer that the role of fluorides is a pharmacodynamic one, like that of aspirin or any other drug. The term "mass medication" is manifestly appropriate today, since there is no proof whatever of a physiologic or nutritional requirement for rather large quantities of an inorganic fluoride every day.

Since the mode of action of fluorides is still obscure, and since dental caries is not a communicable disease, or a disease with a known high mortality rate, there is no need for unrestrained haste in prescribing fluorides internally. This argument appears doubly appropriate since it is quite possible that other technics for fluoridating children can be developed, so that it will not be necessary to compel everyone in a community to submit to a procedure of incompletely measured value.

It is more than likely that scientific efforts directed toward a clarification of the many subsidiary problems created by the proposals to treat entire populations with fluorides will, in the long run, do more to obliterate the existing "no-man's land" between medicine proper and its presently autonomous subdivision of stomatology than has been achieved by the pronouncements of all those who, for a long time, have recognized the artificiality of the educational system which has distinguished between the contents of a course for prospective physicians and that designed for training prospective dentists. Thus a great deal of good may eventually come from the present controversy regarding fluoridation.

Dr. HEDRICK (presiding). Are there any questions?

Dr. MILLER. Doctor, this is an excellent statement that you have submitted. I would, of course, feel better if it was backed up by a lot of other data, other experiments, other than your own statement and conclusions.

Of course, I suppose that it is only by carrying on experiments intensively over a period of years: you can answer whether fluoridation of drinking water is good or bad for people. Let me ask you this: In your city in Massachusetts, do you use topical applications of fluorides to children's teeth?

Dr. HURME. We do not use them as a routine procedure but 2 or 3 years ago we ran a little topical application study which led us to the conclusion that the generally given percentage of reduction of about 40 percent is an exaggeration of the benefits.

Our computations gave a reduction figure of about 11 percent and even that, we feel, is not conclusive.

We were also left with the impression that the topical application technique requires so much time and care that in the long run we are not much better off than we were with the generally accepted method of cutting into the teeth and filling them.

Dr. MILLER. The American Dental Association and the American Medical Association and several public-health groups have recommended for general use the fluoridation of water. Do you think that they have carried on sufficient experiments to justify their recommendation?

Dr. HURME. Of course, in the Forsyth Dental Infirmary for Children we have been intensely interested in these questions because we are an institution devoted to the care of children.

Despite our very best efforts, and we have people who can read more than one language, we cannot find published evidence that would give us the impression that these organizations have done much original work of their own, if any.

In other words, we have the impression that they are simply endorsing each other's opinions.

Dr. MILLER. I believe they agreed, too, that it is of more help in children than it is in adults.

Dr. HURME. That seems to be the general feeling.

Dr. MILLER. Would you say that this committee should now make recommendations, after the testimony that we have had regarding this, and what recommendations do you suggest that we make to the public?

Dr. HURME. Well, in my capacity as a director of clinical research, which is my official title, I would be very enthusiastic if certain recommendations would be listened to and acted upon.

For my own part, I would like to see much more and much better animal experimentation, just as a preliminary.

I would be very anxious to see enough cooperation and interest by our medical colleagues so that we would have competent—I stress competent—medical studies of this problem so that we would know, for instance, whether children or adults with kidney disease, or diabetes, or fracture of bones, or thyroid disturbances, or tuberculosis, or what have you, eliminate fluorides as efficiently as normal people do.

I can find no record of any such studies, but I do find some fragmentary reports which indicate death in case of damage to the kidneys.

I would like to see the development of better statistics in this matter and more adequate observations on which these statistics are based; in particular, better statistics on peridontal conditions which become very important in the aged. More teeth are lost because of pyorrhea than dental decay.

Also, I would like to see better statistics on the mottling of teeth.

I would like to see a serious attempt made to find other means of fluoridation like, for instance, fluoridating milk, as we now fluoridate salt.

I would like to see much more frank discussion of the pros and cons of this matter in those communities where fluoridation is recommended, because in very few instances have I seen such discussion.

I was in Evanston myself when the Evanston study was announced and there was no awareness, to my knowledge, among the population that this was to be wished upon them.

I would also like to see those communities that wish to experiment with this technique to set up their own local controls because, as I mentioned in my statement, there are some very important factors that enter into this picture, geographic factors, heat, humidity, the chemicals in the natural water supplies in the area, and the food supplies.

There are ethnic factors which are very important. We know, from clinical studies, that there are genetic factors which are tied up with the ethnic.

I am of the opinion that regardless of the results obtained in Evanston or Newburgh, these findings may not necessarily apply in full to other communities in the country which have altogether different terrain and climatic conditions.

Dr. MILLER. Doctor, would you recommend that a study be made of the effects to show what is happening when industry uses water that has been fluoridated, when it is forced to use such water, the effects of such uses of water as preserving fruits and canning of foods and the manufacture of beer and other industrial uses of water?

Dr. HURME. I think it would be only common sense to say that industry from the long-time standpoint, might benefit from conducting such studies.

Dr. MILLER. There might be some changes in the product occurring if they used fluorinated water.

Dr. HURME. Absolutely.

Dr. MILLER. That is all, thank you.

Dr. HEDRICK. Mr. Kleinfeld.

Mr. KLEINFELD. Doctor, at one point you mentioned fluoridating salt. Did you mean iodinating salt?

Dr. HURME. Did I say "fluoridating"? I meant iodinating salt.

Mr. KLEINFELD. Dr. Hurme, you may have told us, but when was the Forsyth Dental Infirmary for Children established?

Dr. HURME. As I recall from the records I have seen, the first children were admitted for treatment in 1915. It is the oldest institution of its kind in the country.

Mr. KLEINFELD. Where does it obtain its funds?

Dr. HURME. The Forsyth brothers left an endowment of a few million dollars upon the income of which this institution operates.

Mr. KLEINFELD. Would you call it a philanthropic organization?

Dr. HURME. Yes. The children are only charged a dime, just so that they would not feel like they were charity patients.

Mr. KLEINFELD. A dime?

Dr. HURME. A dime.

Mr. KLEINFELD. How long, Dr. Hurme, have you been personally interested in the problem of the fluoridation of drinking water?

Dr. HURME. I became somewhat more interested than ever before when I learned when I was in Evanston that in the near future they would put fluoride in the water and I was a bit shocked because there had been no publicity about this matter that had come to my attention. So, I began to study up on it.

Mr. KLEINFELD. Well, at that time did you make a comprehensive study of the partinent medical literature?

Dr. HURME. At the University of Illinois I had considerable time for conducting research and I had been reading rather extensively on all the problems relating to the etiology and treatment of dental disease, particularly caries, which is the area of my most intense interest.

Mr. KLEINFELD. Have you examined the present literature involving this particular field, that is dental caries and so on?

Dr. HURME. To the best of my ability I have, although the literature now is so extensive that it would take a lifetime to read all of it.

I would like to add here that prior to going to Illinois I had carried on in New Haven a little study dealing with what some people would call mottling of teeth, a study which was reported in 1948, or thereabouts, in the American Journal of Diseases of Children. The study dealt with the development of teeth in a New England community and the relation of developmental defects of tooth enamel to fluorine toxicosis. As a result of this study I concluded that nobody, not even Dr. Dean, knew for certain how to define mottled teeth or mottled enamel.

Mr. KLEINFELD. Is not observing decay in a tooth a somewhat subjective matter?

Dr. HURME. There is a very high degree of subjectivity to it. Only by accident will you have two equally competent doctors examine a mouth and find precisely the same number of lesions in the teeth.

Mr. KLEINFELD. Do you resolve that uncertainty by utilizing the X-ray?

Dr. HURME. The X-ray helps very greatly in minimizing variable factors.

I would say that Dr. Blayney, for instance, is doing a better job than some others, because he utilizes X-rays.

Mr. KLEINFELD. Well, what are the reasons in your opinion for the apparent discrepancies in the reduction of the rate of dental caries in those communities which are fluoridating water supplies? We have had figures such as 20, 30, 50, 65. Is that true—do these figures vary that much?

Dr. HURME. The figures vary tremendously and there are also figures which are completely out of harmony. There are reductions even without fluoride, in some areas.

Mr. KLEINFELD. How do you explain that?

Dr. HURME. It is impossible for me to give a completely satisfactory explanation of this amazing discrepancy, outside of saying that there is this matter of personal bias.

Examiners in many instances probably having a certain end result in mind and so, whether they intend to or not, their figures tend to verify their concept.

From my study of the literature, it appears that the earliest figures recorded on the relation of mottling, or dental fluorosis and decay of

teeth—show much smaller differences than do the figures obtained in later years. This is very interesting, because in those early days the role of fluorine was not known.

Mr. KLEINFELD. Then, if you have two cities being used for one of these studies, one a control city and one an experimental city, in trying to determine the reduction in the incidence of dental caries, are you saying that the examiners should be the same for both the control and the experimental cities?

Dr. HURME. There would be a certain danger, I suspect, in having the same examiners because the same examiners would know when they were in one city and when they were in the other city and, without intending it, there might be bias in one direction or the other—as I say, without intention.

Mr. KLEINFELD. Well, that would be the same whether the examiners were the same for both cities or whether there was a different examiner for each city.

Dr. HURME. It would be much better if the experiments were so conducted that the subjects receiving fluoride treatment were unknown to the examiners and that the examiners were unbiased people who had no special interest in the outcome.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Miller?

Dr. MILLER. I suppose if you were a health director in the District of Columbia you would not advise the District Commissioners to fluoridate the water.

Now, they are pushing fluoridating of water in the District of Columbia. If you were advising them, would you say that it was a little bit premature, would you tell them, "Go ahead, boys, it is a fine thing; we ought to have it"? Or what would you say?

Dr. HURME. Well, I do not understand how, in view of the statements I have made, I could say it was a fine thing. I would say it is premature.

Dr. MILLER. Of course, your statements do not coincide with the figures or statements of other scientists we have had. It is terribly confusing to me, although it does appear that none of this is confusing to the Commissioners, because they know everything.

One of the Commissioners said, I read his statement a while ago, he said that he was not very much concerned with what the scientists said about holding up the fluoridation of water, he was going to go ahead anyway. Of course, a Commissioner has to know everything about everything. I suppose he reached his conclusions and his opinions by what he read. Well, we form ours by what we hear and read from gentlemen like you.

Now, I guess that you are telling this committee that we should not recommend to these cities, "Sure, everybody should have fluoride in the water; it is good for them." I believe you are not recommending that.

How would you react if you were sitting at our end of the table and writing the report as we will have to write it?

Would you weigh all of the evidence and form a conclusion or just take your viewpoint? If you were writing our report, what would you say?

Dr. HURME. I would simply say that this thing looks good as of this date but we do not have enough evidence to justify medicating every single soul in the community with this chemical until we know more about it.

Dr. MILLER. I think that is all.

The CHAIRMAN. Thank you, Doctor.

Mr. KLEINFELD. We have no other witneses today.

The CHAIRMAN. The committee will meet again next Tuesday, February 26, at 10 o'clock.

(Whereupon, at 12:25 p. m., the committee recessed, to reconvene at 10 a. m., on Tuesday, February 26, 1952.)

CHEMICALS IN FOODS AND COSMETICS

TUESDAY, FEBRUARY 26, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess., continuing the investigation and study begun under authority of H. Res 323, 81st Cong., 2d sess.), at 10 a. m. in room 445, Old House Office Building, Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney, of New York; Jones, of Missouri; Miller, of Nebraska; McDonough, of California; and Horan, of Washington.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will be in order.

Mr. Kleinfeld, call the first witness.

Mr. KLEINFELD. Dr. Neumann.

The CHAIRMAN. Give your name and address to the reporter, Doctor.

Dr. NEUMANN. Hans H. Neumann, 1377 Kew Street, Hewlett, N. Y.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF HANS H. NEUMANN, M. D., HEWLETT, N. Y.

Mr. KLEINFELD. Dr. Neumann, what degree do you hold?

Dr. NEUMANN. An M. D. degree.

Mr. KLEINFELD. Where did you obtain that degree, Doctor?

Dr. NEUMANN. In Vienna in 1932.

Mr. KLEINFELD. What has been your professional career since you obtained your degree of doctor of medicine?

Dr. NEUMANN. I was interested in tropical medicine, and I spent many years in the Pacific and in the Mediterranean and the Near East, and since 1943 I am in New York.

Mr. KLEINFELD. In what capacity were you in those areas which you mentioned?

Dr. NEUMANN. At first I took postgraduate courses and I studied tropical diseases.

Mr. KLEINFELD. Where?

Dr. NEUMANN. In the Mediterranean area. I was in southern Italy, and then I passed through India and Ceylon, and I was later in the New Zealand Government service in the health department as medical officer. I worked in the Samoan Island group where I had

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to take care of the medical needs, and also, for some brief times off and on, the dental needs of the population.

Mr. KLEINFELD. What position do you hold now?

Dr. NEUMANN. I am research assistant at Columbia University at the department of dental research.

Mr. KLEINFELD. What kind of work do you do?

Dr. NEUMANN. I work only on the problem of dental decay.

Mr. KLEINFELD. Have you written any scientific papers on the subject of dental decay which have been published in professional publications?

Dr. NEUMANN. I have written 12 papers, and 2 more are in press at the present time.

Mr. KLEINFELD. What subjects have your papers covered?

Dr. NEUMANN. These papers that I just mentioned were on caries incidence and caries cause.

Mr. KLEINFELD. Will you please read your statement, Doctor?

Dr. NEUMANN. Pursuant to your request I am stating below my views on fluoridation and its effect on prevention of caries.

I am unable to give any opinion on the possible toxic effects of water fluoridation upon the general public. Extensive pediatric examinations in the Kingston-Newburgh study—Schlesinger and coworkers—seem to indicate that no toxic effects should be expected from the presently proposed amounts of fluorides added to the drinking water. This study should, in my opinion, be supplemented by a geriatric study. Fluorine is excreted readily by the normal kidney. Possible toxic effects would occur rather in an age group in which renal impairments of various types are more common; that is, in the old-age group. Presumably no toxicity would be found; yet I believe that a similar study is indicated.

My personal views on water fluoridation are summed up in the following points:

1. With the great difficulty of an objective appraisal of the number of incipient cavities in any dentition, it is too early to state to what degree water fluoridation actually protects the teeth of youth from decay. I therefore believe that the pilot studies should first be continued for 10 years, as originally planned, before arriving at any definite conclusion.

In caries studies in general the authors emphasize wherever possible that the investigator had no knowledge whether an individual under examination belonged to an experimental or control group. This frequently found statement in itself acknowledges and reaffirms the ease of self-deception in scrutinizing objectively incipient caries.

To give examples of the wide range of illusion in caries estimation, I quote the Gottlieb impregnation method, which was described by its author, an outstanding scientist in the dental field, as reducing caries by over 60 percent, even 80 percent. This method was used throughout the country by a large number of dentists and was taught over many years. Recently, though, a study by Dr. Ast concluded in describing the method as worthless, and it fell since in disfavor.

Similar vast differences in findings exist regarding ammoniated dentrifices and other agents.

Determination of caries experience in the same age groups in Evanston, Ill., carried out by two independent investigators found a dif-

ference in caries experience of 32 percent without change in the fluorine content in the water.

Evaluation in fluoridation studies should therefore be carried out by radiological examination only, and the examiner should have no knowledge as to the locality the films originated from.

2. Looking over the reports on the effect of experimental water fluoridation, beginning 1946 and before, their results are not by any means unanimously recommending the procedure. While the experiments in Newburgh, N. Y.; Grand Rapids, Mich.; and Sheboygan, Wisc., induced the observers to great optimism, the authors of a report on the Evanston, Ill., study consider their findings far from conclusive; and a study from Ottawa, Kansas—C. A. Scrivener—which began in 1946 was reported to have resulted in a deterioration of the dental condition of the children.

The number of controlled studies which started early enough for any conclusions is rather small and not uniform in their results.

3. In Australia the natives were endowed with wonderful dental outfits with almost complete absence of caries. Upon adoption of a modern diet their dentitions disintegrated within one generation to the same sorry state as those of the British colonists. The change from the best teeth in the world to the very poorest—much worse than in this country—without any change in the fluorine intake or in the drinking water shows that fluorine has a very limited significance in caries genesis.

Similar observations were made among the Bantu, Maoris, and Eskimos, and practically among all native races.

At this point it may be added that many areas whose water is practically fluorine-free have very excellent teeth, which further cautions in attributing too much consequence to fluorine.

4. The hidden peril of the process of water fluorination lies in the wide acceptance of the incorrect notion that fluorine deficiency accounts for susceptibility to caries and in the accompanying undue complacency.

5. Public-health dentistry is presently possessed with fluorination. There is good reason to draw attention to the much larger local differences in caries incidence in various countries which are not accounted for by fluorine.

The fact that all these remarks underline the negative aspects of fluorination does not purport to deny its merits for which, though, you probably have an ample number of witnesses from the various public health departments and which I therefore do not attempt to describe.

I repeat that these are my personal views on the matter.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Neumann, on the first page of your statement you say that pediatric examination seem to indicate that no toxic effect should be expected from the presently proposed amounts of fluorides added to the drinking water. Is that correct?

Dr. NEUMANN. Yes.

Mr. KLEINFELD. Are you familiar with the literature on the subject?

Dr. NEUMANN. I believe so.

Mr. KLEINFELD. You follow your statement by saying that this study should, in your opinion, be supplemented by a geriatric study. Why is that?

Dr. NEUMANN. I believe that any toxic effect may appear in an individual with impaired kidneys. A normal individual may properly take care of fluorine in much larger quantities, but it definitely is a toxic substance if ingested beyond a certain amount. How an individual with impaired kidneys is able to excrete the fluorine, I do not know. And to my knowledge there is no such study.

As impaired kidneys are more common in old people with arteriosclerosis or with hypertension, I believe that a similar study would be indicated.

Mr. KLEINFELD. For example, we have been informed that in the experimental cities, such as the city of Newburgh, N. Y., which have been fluoridating their water, only children have been examined. In other words, as you point out, only pediatric studies have been conducted. Do I understand you correctly to say that you believe similar studies should be conducted with older elements of the population of these cities?

Dr. NEUMANN. I believe so, or at least in a group of people with not perfectly functioning kidneys. And in every group of population there will be a certain small percentage with impaired kidneys.

Mr. KLEINFELD. Is it a fact, Doctor, that the proportion of middle-aged and elderly people is becoming larger due to the progress of medicine, better nutritional standards, and so on?

Dr. NEUMANN. Yes.

Mr. KLEINFELD. And is it not this segment of our population which furnishes the medical profession with most of its problems in the treatment of degenerative diseases?

Dr. NEUMANN. Yes.

Mr. KLEINFELD. So that, as I understand you, you feel that it is important that this growing important segment of our population be studied to see whether or not the fluoridation of drinking water has any effect upon them?

Dr. NEUMANN. I believe so. The chances are that it is innocuous. Yet I believe that one would feel better about it if it were proven to be nontoxic.

Mr. KLEINFELD. Dr. Neumann, do diabetics drink more water than persons who do not suffer from diabetes?

Dr. NEUMANN. Generally; yes.

Mr. KLEINFELD. Then if water is fluoridated, diabetics will be drinking considerably more water than the ordinary person; is that correct?

Dr. NUEMANN. This is possible; yes.

Mr. KLEINFELD. Do you think that is a problem or not?

Dr. NEUMANN. It could be in uncontrolled diabetes.

Mr. KLEINFELD. What do you mean by "uncontrolled diabetes"?

Dr. NEUMANN. Diabetics not controlled by insulin and by diet consume much more water.

Mr. KLEINFELD. Do you know, Dr. Neumann, of any areas outside of this country where fluorine occurs naturally in drinking water?

Dr. NEUMANN. There are many areas all over the world where fluorine occurs in varying amounts in the drinking water.

Mr. KLEINFELD. For example?

Dr. NEUMANN. There are variations in the fluorine content of the water in practically every country.

Mr. KLEINFELD. As high as 1 part per million?

Dr. NEUMANN. Yes, much higher than that. In some countries there are reports of very much higher fluorine content with well-known highly toxic effects.

Mr. KLEINFELD. In these areas, do you know whether studies or observations have been made to determine whether there has been a marked decrease in the incidence of dental caries?

Dr. NEUMANN. Yes. Generally it is considered to at least delay the appearance of cavities.

There are many areas without any fluorine in the water where caries incidence is very low. It cannot be said that fluorine in the water is essential for caries prevention. Perfect teeth can occur in areas without any fluorine in the water and are actually common.

Mr. KLEINFELD. Do you know of any areas where fluorine occurs naturally in the water to the extent of 1 part per million or more and where there has not been noted a considerable reduction in the incidence of dental caries?

Dr. NEUMANN. You mean naturally occurring?

Mr. KLEINFELD. Yes.

Dr. NEUMANN. Well, this is very difficult to say, because caries vary very much quite apart from fluorine. In northern Greece there are areas, where the water is practically fluorine free, and caries incidence is extremely low.

The CHAIRMAN. May I interrupt for a moment? In that section of Greece can you pinpoint the reason? Can scientists tell us why the teeth are good, is there any particular reason?

Dr. NEUMANN. This occurs not only in Greece. All over the world there are areas without fluorine in the water and with very good teeth.

The CHAIRMAN. Is it not unusual for only one tooth in a child or an adolescent to have a cavity?

Dr. NEUMANN. Yes. Well, many would believe that it is due to a low carbohydrate intake. I personally do not think so. I have seen excellent teeth also in areas with a very high carbohydrate diet. I believe it is the degree of mastication that goes with certain diets, which is more in correlation to good or poor teeth than any other factor. This is my opinion, after having seen teeth in many countries and observed diets and the chemical composition of the food.

The CHAIRMAN. Dr. Miller has a question.

Dr. MILLER. Have you any observation on the teeth of Eskimos where they have little or no carbohydrates?

Dr. NEUMANN. I know that the Eskimos had very good teeth up to the day they changed to a modern diet, and then their teeth deteriorated very rapidly: There is a sudden change from vigorous function to a cooked, soft diet with loss of function of the teeth.

Dr. MILLER. Do not the studies show that the Eskimos who have not gone into this modern diet, who live on seal and high protein diet and do not come in contact with candy bars and so forth, still have good teeth?

Dr. NEUMANN. Yes.

Dr. MILLER. Is that not right?

Dr. NEUMANN. Yes, they still have. Many natives who are on their own old diets still do have very good teeth.

Dr. MILLER. And when they began to get the modern diet, candy bars and cooked cereals and a lot of things we think we have to have, the teeth began to show deterioration?

Dr. NEUMANN. Yes. Modern diet, yes. But which part in the modern diet, I believe is an open question.

Dr. MILLER. That is all.

Mr. KLEINFELD. I would like to get your opinion on this, if you have one: Let's take two cities in different parts of the country. Let's take, for example, Washington, D. C., and Tucson, Ariz. Let's assume for the sake of argument that the drinking water of both cities is free from any substantial fluorine content. Let's assume we find out that adding 1 part per million of sodium fluoride to the drinking water of Tucson, Ariz., will retard appreciably the incidence of dental caries in children, and that no mottling occurs.

Now from those facts which we observe in a city such as Tucson, Ariz., are we safe in assuming that the same amount of sodium fluoride in the drinking water of a city such as Washington, D. C., will result in reducing the incidence of dental caries?

Dr. NEUMANN. Well, opinions have been expressed on this point, I think, that it would depend upon the climate of the place. According to the climate, the water consumption would vary, and therefore a hotter or drier climate should have a lower addition of fluorine. This has been expressed, and I believe it is also the practice to add different quantities.

Mr. KLEINFELD. In your opinion, might different diets have some bearing on the problem?

Dr. NEUMANN. I do not believe that the chemical composition of the diet has much influence on the state of the teeth.

Mr. KLEINFELD. How about differences in racial strains—might that be a factor?

Dr. NEUMANN. In racial strains?

Mr. KLEINFELD. Yes.

Dr. NEUMANN. This was one of the experiences that struck me most. It appears that all human races are equally susceptible to caries.

Mr. KLEINFELD. You have engaged in dental research since what year, Doctor?

Dr. NEUMANN. At Columbia I have been working on the caries problem since 1946.

Mr. KLEINFELD. In connection with your work, have you observed mottling of teeth?

Dr. NEUMANN. Occasionally; yes.

Mr. KLEINFELD. Due to fluorine?

Dr. NEUMANN. Yes.

Mr. KLEINFELD. Is mottling, even a mild mottling, to be considered in your opinion an abnormal condition?

Dr. NEUMANN. Yes; I believe it is a toxic effect of fluorine.

Mr. KLEINFELD. In your opinion, Dr. Neumann, do you believe from your examination of the pertinent literature and from your personal research work and observation that you would recommend to the ordinary city in this country that it fluoridate its drinking water?

Dr. NEUMANN. I would prefer it if the point of toxicity in kidney impairment were first investigated.

Mr. KLEINFELD. Suppose, Doctor, you were practicing medicine in Newburgh, N. Y., which has chosen to fluoridate its drinking water for a 10-year experimental period, and you had a patient in his 60's in that city with a definite kidney impairment. What would you do, if anything, about his drinking water?

Dr. NEUMANN. I would watch rather closely, especially if there were any complications affecting the joints or the bones.

Mr. KLEINFELD. That is all.

The CHAIRMAN. Mr. Jones?

Mr. JONES. No questions.

The CHAIRMAN. Dr. Miller?

Dr. MILLER. How long have experiments on the use of fluorides in water been carried on? How far back do they date?

Dr. NEUMANN. The artificial fluoridation?

Dr. MILLER. Yes.

Dr. NEUMANN. To my knowledge around the year 1945, 1946.

Dr. MILLER. About 7 years?

Dr. NEUMANN. Yes.

Dr. MILLER. Do you think the experiments that have been carried on to date are conclusive in their findings?

Dr. NEUMANN. We have had many disappointments in caries control, and I would rather wait for more figures.

Dr. MILLER. Doctor, you confuse me. I thought you said a few minutes ago you would recommend we go ahead and use it, and now you say we ought to wait for a little more study and control. Do you think we ought to have more study on it before we recommend cities to go ahead and use it, or do you think we ought to go ahead and put in fluorine as mass medication without any further study?

Now just where do you stand? Do you have a line of demarcation you can tell us, or do you want to be just on both sides of the fence a little bit?

Dr. NEUMANN. I would wait for more evidence.

Dr. MILLER. As a legislator we have to make some recommendations. Now, if we get on both sides of the fence at this time people do not know where we are. I may be wrong in my conclusions and you may be right, but we have got to make some recommendations. I am wondering as a scientist whether you would say to people, "Sure, sodium fluoride is great stuff. Everybody ought to use it."

In my home town, Kimball, Nebr., where I live, they had a meeting and are discussing fluoridation of water. I think that emanated from this committee, Mr. Chairman, because I wrote a little article for the local press, and maybe I should have kept still because I stirred up something that was sleeping, although I think we ought to give the people all the information they want.

The American Medical Association, the Dental Association, and Public Health all say it is fine. Then I pick up the testimony of Dr. Harris of M. I. T. and Dr. Alfred Taylor, of the University of Texas——

Dr. NEUMANN. Yes.

Dr. MILLER. And some others, and they make statements like—fluorine is used in rat poison, and they are not ready to recommend it for general mass medication.

Now where do you stand on this thing? What am I going to tell these people?

Dr. NEUMANN. Well, I would rather wait for a period of time and have some more definite opinions. There are recommendations on the part of the American Dental Association and the American Medical Association and the National Research Council and by innumerable authorities, who all base their statements on each other's recommendations, and none of them have made any research themselves. It all goes down in the end to the five studies that have been going on for several years.

Dr. MILLER. There are some experiments still being carried on, though, that have not been concluded; is that right?

Dr. NEUMANN. A number. None of them have been concluded.

Dr. MILLER. It is a little hard in 7 years' time to say what the effect of sodium fluoride in water would be to the lifespan of the human being, is it not?

Dr. NEUMANN. That would be impossible.

Dr. MILLER. It would be impossible, would it not?

Dr. NEUMANN. Yes.

Dr. MILLER. Whether it shortens your life or what it does to the kidney or liver or other functions of the body, it would be impossible to say?

Dr. NEUMANN. Yes.

Dr. MILLER. From the experiments that have been carried on for just 7 years?

Dr. NEUMANN. Yes.

Dr. MILLER. Then if we say to these towns that are contemplating the use of fluorine in water—we might say that investigations have not been completed, and there is a difference of opinion among scientists, that 7 years is too short a period to know whether we should resort to a mass medication of the water with fluorine in order to attack the problem of caries in teeth. Is that right?

Dr. NEUMANN. Yes.

Dr. MILLER. Does fluoride unite with anything in the water and form a chemical reaction? Some water has calcium, magnesium, and some other chemicals.

Dr. NEUMANN. Yes.

Dr. MILLER. Is there a chemical reaction?

Dr. NEUMANN. It is ionized and would not.

Dr. MILLER. Ionized and would not. And would not form a reaction?

Dr. NEUMANN. No.

Dr. MILLER. When you boil the water does fluorine go off like chlorine, does it disappear or stay in the water?

Dr. NEUMANN. No; it will stay in the water.

Dr. MILLER. And if grandmother's teakettle is left on the stove and the water boiled in it day after day and year after year, and she gets some salts in there, what would they be in there with fluorine added to the water?

Dr. NEUMANN. This is one of the confusing points. The same refers to tea.

Dr. MILLER. Yes.

Dr. NEUMANN. Tea has a very high content of fluoride. The English are the biggest tea consumers, yet their teeth are among the worst.

Dr. MILLER. That was going to be my next question. If grand-

mother invited me to have a cup of tea and she pours it out of the kettle with all the salts in there, would I get an extra dose of fluorine I might not need?

Dr. NEUMANN. Probably not.

Dr. MILLER. What would the fluorine do in wine—many people drink wine—or beer or preserved fruits and things like that? Would there be any reaction in the chemicals to beer, wine, and fruits, and so forth?

Dr. NEUMANN. Anything I could say on this matter would be only opinion because I have not investigated it.

Dr. MILLER. No studies carried out on it as yet?

Dr. NEUMANN. No.

Dr. MILLER. And experiments might show there is some chemical reaction or some difficulties might develop?

Dr. NEUMANN. Possibly. I would not be able to say.

Dr. MILLER. Do you know of any experiments being carried on along that line?

Dr. NEUMANN. Not to my knowledge.

Dr. MILLER. I think that is all, Mr. Chairman.

The CHAIRMAN. Mr. McDonough.

Mr. MCDONOUGH. Doctor, are you familiar with whether fluorine was first observed in drinking water as a detriment or a benefit?

Dr. NEUMANN. Detriment.

Mr.MCDONOUGH. As a detriment?

Dr. NEUMANN. Definitely so.

Mr. MCDONOUGH. And now it is being looked at as a benefit in certain limited quantities?

Dr. NEUMANN. Yes.

Mr. MCDONOUGH. We have had testimony up to now that one part per million seems to be more beneficial than detrimental.

Dr. NEUMANN. This is the claim, yes.

Mr. MCDONOUGH. Do you agree with that?

Dr. NEUMANN. I do believe that with one part per million, there would be no toxic effects. I believe generally with the limitation that I made before that is true.

Mr. MCDONOUGH. You believe more beneficial effect than detrimental effect in one part per million?

Dr. NEUMANN. Yes, if the excretion is good.

Mr. MCDONOUGH. In other words, I understand you to say it is more beneficial at one part per million than it is detrimental at one part per million?

Dr. NEUMANN. This is being claimed.

Mr. MCDONOUGH. I mean, do you agree?

Dr. NEUMANN. Yes.

Mr. MCDONOUGH. In other words, do you think that water with one part per million of sodium fluoride added is more beneficial than if no fluorine were added to the water?

Dr. NEUMANN. Provided that it has no toxic effects on a few. It may be very beneficial to the many, but it may possibly be toxic to a very few.

Mr. MCDONOUGH. And if it were toxic to a very few, you would think it would be detrimental?

Dr. NEUMANN. Certainly.

Mr. McDonough. Well, of course, that could apply to most anything. I mean, after all, almost anything that is beneficial to most everyone that is not detrimental to a few?

Dr. Neumann. Yes.

Mr. McDonough. You are aiming at perfection in that instance, and, of course, we cannot assume that we are going to be perfect in doing anything that is beneficial to a large number but may be detrimental to a few.

Dr. Neumann. That is so.

Mr. McDonough. And if it is detrimental to a few, you think it is not desirable?

Dr. Neumann. If it is detrimental to a few, I believe it is not desirable. The degree of protection is not high enough to warrant toxic effects even on a few.

Mr. McDonough. Is there any other ingredient in water or anything else that could be added to water that would be as beneficial as fluorine in 1 part per million?

Dr. Neumann. Chlorine addition to water has definitely proved its value.

Mr. McDonough. Well, the reason I am asking that is that fluorine seems to be the one chemical that we are talking about.

Dr. Neumann. Yes.

Mr. McDonough. In adding to the water 1 part per million, that is presumed to be beneficial to a large number.

Dr. Neumann. Yes.

Mr. McDonough. Is there any other chemical that you know of that is under consideration to be added to drinking water that would be beneficial to a large number of people in addition to fluorine?

Dr. Neumann. No.

Mr. McDonough. Do you know of any other chemical under consideration?

Dr. Neumann. Outside of the various fluorides—there are many different fluoride preparations—no, sir.

Mr. McDonough. Chlorine is added.

Dr. Neumann. Yes, chlorine has been added. Chlorine has been added for many years for entirely different reasons, as a bactericide.

Mr. McDonough. That is all.

The Chairman. Thank you, Doctor.

Dr. Neumann. Thank you.

The Chairman. Call the next witness.

Mr. Kleinfeld. Dr. Margaret Smith, please.

The Chairman. Give your name and address to the reporter.

Dr. Smith. Dr. Margaret Cammack Smith, University of Arizona, Tucson.

(The oath was administered by the chairman.)

The Chairman. You may proceed.

TESTIMONY OF MARGARET CAMMACK SMITH, PH. D., FORMER HEAD, DEPARTMENT OF HUMAN NUTRITION, UNIVERSITY OF ARIZONA, TUCSON, ARIZ.

Mr. Kleinfeld. Dr. Smith, what degrees do you hold?

Dr. Smith. I hold the degree of master of science and Ph. D. degree.

Mr. KLEINFELD. Where did you receive your degrees?

Dr. SMITH. My doctor's degree at the University of Columbia.

Mr. KLEINFELD. When did you receive that degree?

Dr. SMITH. 1925.

Mr. KLEINFELD. What has your professional career consisted of since that year?

Dr. SMITH. During that time when I was studying for my degree I taught chemistry at Teachers' College of Columbia University, and then I went from there to the University of Arizona, and taught nutrition and also did experimental research in the experiment station of the University of Arizona Agricultural College for years.

Mr. KLEINFELD. For how many years?

Dr. SMITH. Twenty years at the University of Arizona and seven years at Columbia.

Mr. KLEINFELD. And you were head of the department of human nutrition at the University of Arizona?

Dr. SMITH. And also of the nutrition research department in the agricultural experiment station.

Mr. KLEINFELD. What would you say your special field of professional interest is?

Dr. SMITH. In nutrition.

Mr. KLEINFELD. How long, Dr. Smith, have you been engaged in studying fluorine in drinking water and elsewhere?

Dr. SMITH. Since 1930 to about 1943 or possibly 1944. I was actually engaged in research along that line since then.

Mr. KLEINFELD. How did you happen to become engaged in research study on fluorine?

Dr. SMITH. Because my interest was aroused in the occurrence of defective teeth in Arizona. That interest was called to my attention by a local dentist.

Mr. KLEINFELD. Dr. Smith, will you please read your statement?

Dr. SMITH. I have been asked to express my views on the proposed plan for mass control of dental caries by fluoridation of public water supplies.

Let me make it clear in the beginning that I recognize the value of fluorine in the reduction of the incidence of dental decay. I am familiar with and accept the veracity of the outstanding work and findings of the United States Public Health Service regarding the relation of dental caries experience and the fluorine content of the drinking water supply. This has been shown both by epidemiological data from areas in which fluorine naturally occurs in the domestic waters and also by experimental studies of shorter duration in which fluorine has been artificially added.

However, in spite of these findings, I am at this time opposed to the wide acceptance of the plan to inhibit dental caries by increasing the ingestion of fluorine by means of artificial enrichment of potable water supplies in all parts of the country. In my opinion there are many ifs and buts against such a Nation-wide plan.

May I first paint a picture which was presented to me in 1930. At that time, as head of the department of human nutrition in the Arizona Agricultural Experiment Station, my attention was called by a group of local dentists headed by Dr. Alex Bard, formerly on the staff of the School of Dentistry at the University of Pittsburgh, to the prevalence in Arizona of a very ugly disfiguring dental defect

known then as mottled enamel. Its cause had baffled the dental profession since it was first reported in this country in Colorado Springs in 1916. Because of the seemingly logical possibility of it being a defect of nutritional origin, with the approval of the University of Arizona authorities, I began the search for its cause in June 1930.

It does not seem necessary at this time to review the details of the various methods of approach to this problem. Suffice it to say that before the end of the calendar year my colleagues and I had produced mottled enamel in rats experimentally and proved beyond a doubt that fluorine present in the drinking water supply of the afflicted persons in infinitesimal amounts was the offender. Since that time further light has been thrown on the problem and more than 40 papers written by the speaker and her colleagues have appeared in the literature.

Elaboration of our studies on similar lines have since been made by the United States Public Health Service and others and their results have substantiated and given added proof to our findings.

Discovery of this toxic element lead immediately to a State-wide survey of the extent of the occurrence of dental fluorosis in school children in Arizona and the correlation of its severity with the amount of fluorine in their drinking water. Many thousand water samples in Arizona have since been analyzed for fluorine by the Agricultural Chemistry Department. Findings have shown in this State that water having a concentration as low as 0.9 parts per million of fluorine will mar the teeth of its users.

Due then to pleas from Arizonians for aid in wiping out this tooth damage which occurred in certain communities without regard to creed, color, race, economic status, nutritional or dental care, our attention was focused on education of the public regarding its cause and ways and means of preventing its occurrence. Unfortunately in certain Arizona areas it was impossible to find access to water supplies either free from fluorine or containing less than a toxic amount. In 1934, therefore, aid was given by my colleague, H. V. Smith, who developed a fluorine removal filter. In principle its action is based upon the affinity of the calcium apatite of bones and teeth for fluorine and therefore the removal of fluorine in water as it passes through especially prepared activated bone meal. Small portable filters for home use have proved effective, and installations on a larger scale in schools where there was no communal water supply have been beneficial.

Of paramount importance at this time is, however, recognition of the inhibiting effect of fluorine ingestion upon dental caries incidence. The observation first made in this country by Black in 1916 that mottled teeth had less decay than was usually observed in the same age groups with so-called normal teeth went unheralded. It remained for the United States Public Health Service by means of surveys and epidemiological studies to pile up rather conclusive evidence that the rate of dental caries attack is less in inhabitants of communities whose water supplies have a higher concentration of fluorine. This disclosure has stimulated research along many scientific lines and a great deal of valuable information has accumulated which gives both direct and indirect support to their observations, perhaps the most important being the reduction in experimentally produced caries

in laboratory animals by the inclusion of fluorine in either their food or water supplies.

Tooth decay has long been thought of as an unsolved dental disease almost universal in its occurrence. Even partial control has never before been accomplished. The reported findings of the past decade that the use of fluoride drinking water by children during the formative period of their teeth may result in a 40 to 65 percent reduction in dental caries experience have aroused public interest.

Although there are several factors, both known and unknown, involved in optimum formation of teeth before they erupt and during their maintenance through life free from decay, the probability that even partial reduction in caries attack may be brought about by ingestion of fluorine is very appealing. The natural question which arises is how the general public can take advantage of this knowledge? Drinking water is a universal article more uniformly consumed by men, women, and children than any other dietary constituent, therefore why should fluorine not be added to public water supplies and thus make its benefit universal? Such a plan we know was put into operation on a carefully controlled experimental basis by the New York State Department of Health in 1945 and similar studies are being carried on elsewhere at the present time. Although these studies have been planned on a 10-year or longer basis so that the permanent teeth of 6- to 12-year-old school children will have been exposed to fluorine ingestion during their formation, progress reports of great interest have been released. Results are said to show a consistently downward trend in DFM rates with a 32.6 percent reduction after 4 years of water fluoridation at a 1.0 to 1.2 parts per million fluorine level.

Needless to say, findings like this are inspiring and stimulate a public demand for immedate adoption of the plan to fluoridate water in all areas where the water supplies are too low in fluorine to offer the public similar protection from tooth decay. It is not surprising therefore that fluoridation of communal water supplies is being widely advocated as a cheap and easy way to raise the standard of dental health and it is going forward by leaps and bounds. It is popular now to get on the band wagon, for, as asked in the American Journal of Public Health in a summary of the fluoridation problem, "What are we waiting for?"

The American Waterworks Association, spurred on by flattering statements, such as:

> The waterworks profession will be instrumental in helping bring dental caries under a large measure of control in the next generation with the same quiet dispatch and efficiency that has previously characterized the profession's contribution to control typhoid groups, cholera, and dysentery,

in 1949, is said to have given official acceptance to the practice of water fluoridation for the purpose of reducing dental decay. Naturally, too, the interest of the dental profession has been aroused. Many practicing dentists have been imbued with the Public Health's dentists' viewpoint; that is, to quote:

> It is our obligation to see to it that all communities fluoridate their water supplies.

They have been assured, for obvious reasons, that "Even after fluoridation has been in operation for a long period of time and maximum protection reached, the whole dental problem will not have been

solved and more than one-third of the present dental problem will still be present and in need of treatment." Some have cautiously held back to but faint praise of the fluoridation plan because of the fear that unforeseen adverse results might appear later and act as a boomerang.

The snowball, however, has started rolling, and it's getting bigger and bigger. The question is, Will it be stopped or at least slowed up before it has grown so large that it will crush the innocent bystander? Fluoridation does appear to be a desirable program, but let's pause, stop, look, and listen before falling unwittingly into a pit. Let us not forget that fluorine first came on our horizon as an offender, the cause of an unwanted, undesirable tooth defect. Fluorine is not considered an essential constituent of the diet, necessary for normal body composition or physiology. Mottled tooth, mottled enamel, dental fluorosis, or whatever it may be called, is a dental abnormality resulting from the interference of fluorine with the normal calcification and formation of children's teeth before they erupt through the gum line. Mottled teeth appear showing characteristic markings which even in the mildest forms are conspicuous and undesirable. Normal teeth are smooth, glossy, translucent, and are usually creamy white in color. Mottled teeth have lost these characteristics and, instead, have dull chalky-white patches usually distributed rather irregularly over the surface of the teeth, or the whole tooth may present a dull white, unglazed appearance. Attention is often attracted to the mild cases because of a difference in the reflection of light as it falls upon them. In moderate or more severe types, the abnormally calcified areas on the tooth surface may absorb stain—hence the old name "brown stain"—after they have erupted and come in contact with food or other colored organic or mineral material. In most severe cases, of which I have seen so many, the surface of the enamel is pitted and corroded.

For the purpose of record the United States Public Health Service has classified the degree of mottling as "questionable, very mild, mild, moderate, and severe," depending upon the extent of the tooth surface affected and its severity.

I would like to read to you their description of mottled teeth of different types. For example, they have defined the questionable type of mottled enamel as "teeth showing slight aberrations in the translucency of normal enamel ranging from a few white flecks to occasional white spots. Furthermore, in some instances thin irregular, white opaque streaks are noted on the incisors. In other cases the tips of the summit of the bicuspids show an unusual white opacity, the remainder of the tooth being normal. As such cases are not sufficiently developed to be classed as very mild or mild and are definitely not normal they are listed as questionable."

Again, they define very mild type as having "small opaque paper-white areas scattered irregularly or streaked over the tooth surface, principally observed in the labial or buccal surfaces and involving 25 percent of the tooth surface."

Those classified as mild have "white, opaque areas involving at least half of the tooth surface. The surfaces of the molars and bicuspids subject to attrition show thin white layers worn off and bluish shades of underlying normal enamel."

Those are the descriptions given by the United States Public Health Service for different types of mottled teeth. Surely it is obvious that

even the questionable type of fluorosed teeth is a dental abnormality which should be avoided and not desired or classified as normal.

It should be remembered that every case, no matter how mild, has resulted from too much fluorine, usually in the drinking-water supply. Just as there has been found an inverse relationship between dental caries prevalence and fluorine in the drinking water, so it has been known for a long time that the opposite is true for dental fluorosis. There is a very direct relationship between the severity of mottled teeth and the fluorine which is ingested by the afflicted person.

The question of stupendous importance at this time is, therefore, how much fluorine can be consumed without damaging results.

Based upon epidemiological studies the Public Health Service believes that a fluorine concentration in potable water supplies of from 1 to 1.5 parts per million will give the maximum protection against caries and affords minimum threshold for endemic fluorosis. Therefore, they have considered 1 to 1.5 part per million the optimum amount of fluorine to be added to drinking water as a partial control measure, and this concentration is said to fall well within the limits of safety.

There are several reasons why I do not agree with these standards. In the first place, the concentration recommended is based upon epidemiological studies or surveys in which the results are obtained by observation of population groups. Their "index of dental fluorosis" as established for different communities has come not from individual clinical studies but from studies on mass groups in which the individual is important only as a member of that group. Based on such studies, it has been frequently reported that continuous use of domestic water supplies with a fluoride content of 1 part per million will result in mild dental fluorosis in 10 to 12 percent of the inhabitants of the community. We are asked to accept the insignificance of this so-called "sporadic" mottling of the teeth in its mildest form and to view it as of no importance from the aesthetic standpoint.

Let's look into some of these studies from which recommendations for optimum fluorine levels in water supplies for dental caries control have come.

In 20 Midwest cities included in the Public Health Service studies there were 7 which had water supplies naturally providing fluorine at 1 to approximately 1.5 parts per million level or thereabouts. Some a little higher—1.7, I believe. It has been found that these cities have a lower rate of dental decay than was observed in the 13 other communities covered in these studies and I believe it is from these studies that the assumption that fluoride medication will reduce dental caries to the extent of 60 to 65 percent has come.

Certainly the beneficial effect from the standpoint of a lower dental caries experience is impressive. Of importance also, however, is the less stressed dental fluorosis index in these same cities. The percentages of their inhabitants reported as having mottled teeth in varying degrees of severity were as follows: Kewanee, 12 percent; Aurora, 15 percent; Joliet, 25 percent; East Moline, 32 percent; Maywood, 33 percent; Elmhurst, 40 percent; and Galesburg, 48 percent. Cases classified as questionable were not included in these percentages.

Does not the complicating factor of dental fluorosis warrant increasing consideration? Should a community in which less than 10 percent, but nevertheless some, show very mild or more severe types

of mottled enamel be classified as having a "negative mottled enamel index"?

Again, let us look at the 1951 report of the fluoride dental caries relationship in a adult population studied in Colorado Springs. In the author's conclusions of this report, it was stated, and I quote:

> The total rates for decayed, missing, or filled permanent teeth—

that is the DMF—

> were about 60 percent lower in Colorado Springs than in Boulder for each group. The phenomena of caries inhibition continued and diminished through the age of 44 years.

Not appearing in the summary and conclusions, however, you may find that the fluorosis ratings of the 385 natives examined showed but 63 in the combined questionable and normal group, whereas there were 174 who had very mild mottled enamel, 109 mild, 32 moderate, and 7 with the severest type of mottled teeth.

Perhaps attention should be called at this point to the fact that the first report in this country of the disfiguring dental defect known as mottled enamel came from Colorado Springs.

It is true that the Colorado Springs water contains 2.6 parts per million of fluorine, which concentration is not now recommended as desirable for mass reduction of caries, but from what other sources have claims for caries inhibition of this magnitude come? Could it be that maximum reduction of the onset of decay results only from ingestion of fluorine in sufficient amounts to interfere with normal tooth development with resulting mottled teeth, the fluorine exerting its effect as a caries inhibition as a preventive medicine?

The truth still remains that mottled enamel, even in its mildest forms is caused by the toxic action of fluorine and is, in my opinion, an undesired dental abnormality. I fear that many of those who recommend the fluoridation of drinking water to the extent that 10 to 12 percent of its users will have mildly mottled enamel in some form have not seen mottled enamel of any type and are, therefore, not familiar with the psychological effects produced on those having mottled teeth.

In the second place, it should be realized that there are many variable factors which should be understood before a tolerance level for fluorine can be established. There are many communities which have a much higher dental fluorosis index (a higher percentage of mottled teeth of the more severe type) than others having the same fluorine concentration in their domestic water supplies specifically 1 to 1.5 parts per million, the level which has been recommended for caries protection. It has also been found that in certain communities in the South and Southwest the use of drinking water with less than 1 part per million, as low as 0.5 or 0.7, has resulted in mild tooth damage in a certain percentage of the population.

These differences may be explained by differences in climatological factors which would result in a difference in water consumption. Drinking water intake is a variable factor, especially among children. Their water-drinking habits are greatly influenced by their muscular activities and it is difficult to measure normal water intake when they have easy access to the running hose during their play. Certainly much more information on this point than is now available should be

had before a generalized statement of an optimum fluorine concentration can be made.

In the third place, in addition to the uncertainties surrounding drinking water habits, variations in the amount of fluorine in foodstuffs should be taken into consideration. It has been shown by experimental work with animals that fluorine of food-borne origin as well as water-borne is effective, though in all cases not equally so, in producing dental fluorosis and in reducing dental caries incidence. Other experiments with human beings have shown that fluorine of food origin can be assimulated and is available for metabolism. The average daily consumption of fluorine in foods has been calculated for children from 1 to 12 years of age to range from 0.27 to 0.56 milligrams. Thus it would seem that the amount of fluorine provided by the food is less than with that ingested when the water supply contains 1 part per million. There are several factors however which might change this picture. For example there is recent evidence that the fluorine content of plant materials may vary considerably with conditions under which they are grown. Again, it has been found that foods cooked in water absorb some of its fluorine. However, the factor which makes the daily amount of fluorine consumed per person even more unpredictable is the increasing use of fluorine compounds as insecticide sprays and dusts for the control of agricultural pests. The United States Food and Drug Administration having set a legal tolerance level of 7 parts per million of fluorine for apples and pears involved in interstate commerce, has made it possible for an apple to provide about 1 milligram of fluorine, which is approximately the amount furnished by four glasses of water containing 1 part per million. Unfortunately as far as I know there are no State laws which control the use of fluorine containing insecticides on fruits and vegetables grown and distributed within State boundaries. Thus the presence of unknown amounts of fluorine in food should make us more cautious of adding it to our water supplies.

There are still other factors which make it difficult to establish a safe standard for fluoridation of public water supplies. One of these is a familiar difference in reaction to fluorine ingestion, just as there are differences in caries susceptibility.

A great difference in caries susceptibility and the inhibiting action of fluorine has been observed in different strains of laboratory animals—cotton rats—on the same diet. So it has been observed that all children do not get the same protection from tooth decay by the ingestion of the same amount of fluorine and it can also be said that they do not respond equally to its toxic effects. Lower nutritional status as well as a constitutional difference in parent stock has been offered as an explanation for the occurrence of the more serious type of mottling found in certain communities than was found in others whose domestic water supplies contained similar amounts of fluorine. A higher fluorosis index in some cases has been explained by differences in food habits, especially milk intake. Whether the low consumption of milk plays a part because it is replaced by a greater intake of water or because its high calcium content reduces the assimilation of fluorine from other sources, is a disputed question.

It is because, however, of variable features such as these which I have discussed that I wish to raise an objection to any proposed plan for partial control of dental caries by fluorinating public waters at

96568—52—pt. 3——36

this time. Until the undesirable consequences are more widely and thoroughly understood or until the individual can be assured of complete protection from the danger of even the mildest form of fluorosis, I wish to reiterate that, I do not believe that it is a wise procedure or should be advocated. A great deal more data should be acquired to establish the minimum threshold of fluorosis for all people in all communities where such a plan is contemplated. I am not in sympathy with the objection to watchful waiting as presented by the statement, to quote—

> if the process proves worthy of adoption sometime hence, a community denied fluoridation during any period of watchful waiting will have lost the value of the treatment for such a period. Neither is it pleasant to contemplate that such a loss in tooth protection amongst youngsters cannot be made up by subsequent water treatment.

The proponent of this idea has ignored the fact that only partial caries protection has been assured at the possible expense of acquiring damage to the teeth which is irreparable.

Fortunately a realization of the objectional features of artificially fluoridating public waters has led to a search for other possible means of accomplishing the same results in dental health protection, without accompanying dangers or disadvantages. Many lines of attack in different scientific fields have been followed. First sought has been knowledge of the part which fluorine plays in inhibiting dental caries. Though the protective action of fluorine is still not thoroughly understood, some points have been established. Analysis has shown that the fluorine content of both the dentin and the enamel of the teeth varies in magnitude with the amount of fluorine ingested either from water or food sources. It has also been demonstrated that the enamel of teeth containing fluorine is less soluble in certain acids, including those which are accepted as the instigators of tooth destruction. For example, normal enamel has been reported to start to decalcify at a pH of 5.2 wheras fluoridized enamel begins at the lower pH of 4.7. A rather loose concept of the action of fluorine is therefore that it replaces the hydroxyl group in calcium apatite, which is the major component of dental enamel and forms a less soluble fluoro apatite. A definite physical change in the enamel has also been indicated by an increase in its hardness.

Perhaps it should be mentioned in passing that there is a wide range in the fluorine content of teeth among people using the same water supply. This wide range is difficult to understand except by assuming that there have been great differences in the amount of fluorine ingested due to differences in water intake, or a difference in the consumer's ability to utilize, metabolize or excrete the ingested fluorine. Either of these points would explain the apparent differences among people in their response to exposure to fluorine which have already been discussed.

Of great interest is the fact that chemical laboratory tests have shown that powdered enamel taken from the tooth has a great affinity for fluorine and is absorbed directly, the absorption varying in amount to some extent with the concentration and type of fluorine solutions and the length of time of contact. It is experiments such as these which have led to topical application studies and their efficiency in reducing dental caries experience. This method of approach seems

more desirable because fluorine is applied to the enamel surface of already formed teeth, and therefore the interference of fluorine with the development of normal tooth structure during the period of its formation has been eliminated. Studies of this type with laboratory animals, in which the fluorine content of their molar teeth has been increased by painting the tooth surfaces after they have erupted, have shown marked inhibition of dental caries. Results too, after about 8 years of research with more than 1,500 children in various parts of the United States have been very impressive. Approximately 40 percent reduction in dental caries has been reported for quadrants of topically treated teeth. The results have been remarkably uniform for individual children.

The method of topical application has advantage over fluoridation of drinking water in being available to rural communities which have no communal water supplies. Perhaps of even greater advantage and appeal is the fact that fluorine can be offered in this way whenever needed and desired.

Other practices such as use of fluorine-containing dentifrices, mouth washes, tooth powders and pastes, enriching the fluorine content of foodstuffs or adding fluorine to the daily diet of the child during the period of formation of his teeth have been in use.

The ingestion of fluorine from any other source adds to the danger of fluoridating of public water supplies.

It should be realized that there are ways of producing teeth which have a low caries incidence other than the use of fluorine compounds. Recent reports of the use of antibiotics as well as chemicals which interfere with the action of bacteria in the mouth have been encouraging. Let us remember also that perfect teeth have been obtained without the aid of any artificial means. Optimum dietary habits resulting in good nutrition and correct care in cleansing the teeth are all important factors which could, by themselves perhaps, prevent a large percentage of the tooth decay which is now so prevalent.

In closing it should be emphasized that one function of the Public Health Service is to see that public drinking water supplies are safe for human consumption. Hitherto this problem has been accomplished by removal of objectionable features by some means or other. Fluoridation of water introduces an entirely different method for raising public health standards. It is proposed to add a chemical to water supplies used by all people in a community during their life span which will change the structure and composition of the teeth and in this way bring about a partial reduction in caries incidence.

If every person ingested the right amount of fluorine, at the right stage of development of each tooth and responded to its preventive medication in the optimum way, overdosing could perhaps be avoided and blotchy fluorosed teeth not produced. But until we can be assured that overdosing will not become common practice, the plan of fluoridation of public water supplies should be curbed and extreme caution observed, or I fear that the public health measures will stand the risk of becoming a public health hazard.

The CHAIRMAN. Mr. Kleinfeld?

Mr. KLEINFELD. In view of the fact that we have another witness, I will forego any questions.

The CHAIRMAN. I want to thank you, Doctor, for your contribution. It has been most informative, I am sure, to this group here.

I have just this one question. Sea food contains a great amount of fluorine, does it not?

Dr. SMITH. You mean?

The CHAIRMAN. Sea foods?

Dr. SMITH. I did not mention sea foods particularly, but of course fish or fish bones, contain fluorine.

The CHAIRMAN. This is a great fish-eating community right here in Washington.

Dr. SMITH. It is?

The CHAIRMAN. And if we were to add fluorine to the water might that contribute also to the effect upon teeth?

Dr. SMITH. There has been a community, I believe, in one of the south Atlantic islands, Tristan, where a reduced dental caries incidence and some mottled teeth have been reported without fluorine in their water. They again are fish eaters, and probably eat fish bones along with the protein content of the fish.

The CHAIRMAN. Thank you.

Mr. KLEINFELD. May I ask just one question, Mr. Chairman?

The CHAIRMAN. Yes.

Mr. KLEINFELD. You may or may not have any opinion on this question, Dr. Smith.

I asked this question of the first witness this morning. Suppose the water in the city of Tucson, Ariz.—just to pick a city at random—the water is naturally free from fluorine, and we add sodium fluoride to the extent of 1 part per million in the drinking water of that city, and we find that there is a substantial decrease in the incidence of dental caries and no appreciable degree of mottling.

Would you say, in deciding to fluoridate the water supply of a city like Washington, D. C., which also has water which does not contain appreciable fluorine, that we can expect the same results both in the decrease in dental caries incidence and in the amount of mottling?

Dr. SMITH. Of course, I am not a dentist. I have looked at the teeth of almost every school child during a certain period in Arizona, and could just with the eye and not using any dental equipment, see mottled teeth. I have not investigated them myself from the standpoint of dental caries. But I can say this: That cities having the same water concentrations of fluorine will respond entirely differently from the dental fluorosis index standpoint. That is, a different percentage of the consumers of this water will show the toxic effect of fluorine.

So that 1 part per million of fluorine in water, or less, around Arizona, and as low as 0.5 or 0.7, I believe, reported by the health department from certain sections in Georgia, will produce mottled teeth which they define as mild in a certain percentage. But they say, let's accept 10 to 12 percent of the population having mottled teeth and ignore it.

Mr. KLEINFELD. Are you saying, Dr. Smith, that the addition of the same amounts of sodium fluoride in drinking water in different cities may produce different mottling?

Dr. SMITH. Unquestionably.

The CHAIRMAN. Dr. Miller.

Dr. MILLER. You are aware of the fact that the American Dental Association, the public health groups, the American Medical Association, have recommended the use of fluorine in 1 part per million in drinking water?

Dr. SMITH. Yes, I am.

Dr. MILLER. Do you think they have carried on their experiments sufficiently far to justify such a recommendation?

Dr. SMITH. I do not. I think we have plenty of evidence without any further experiments to show that 1 part per million is too high a level to be universally accepted.

Dr. MILLER. Do you know what experiments they have carried on?

Dr. SMITH. I do. I have reviewed the literature pretty extensively.

Dr. MILLER. Are they rather extensive experiments that the dental and public health and medical associations have carried on? Did they carry on some extensive experiments before reporting this recommendation, or do you know?

Dr. SMITH. Well, from one standpoint, I do not think there is any question that their experiments and also their observations have been extensive to the point that fluorine in the water has been found to reduce dental caries. But I say at the same time the danger is, it can do something else which we do not want. Therefore I think they have not gone far enough with their studies in different sections of this country.

Dr. MILLER. And 7- or 8-year experiments with fluorine in water is not long enough time to know what it will do to the span of life of an individual?

Dr. SMITH. Why, no.

Dr. MILLER. That is all.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. You make reference to the use of fluorine in pesticides. That is cryolite, I suppose, you had in mind there?

Dr. SMITH. Reference to the use of cryolite?

Mr. HORAN. Of fluorine. What type of fluorine did you have in mind?

Dr. SMITH. You mean in the water supply?

Mr. HORAN. Cryolite. Is not that a fluorine?

Dr. SMITH. That is a fluorine compound, but not necessarily the way it occurs in water.

Mr. HORAN. Would it be different?

Dr. SMITH. It does not make any difference within limits. I mean as far as whether you have sodium fluoride or whether you have a cryolite—not cryolite, but sodium silicate. They have tried different combinations of fluorine in the water supply.

The point is, if they are soluble to a certain extent, they will ionize, the fluoride that ionizes to the same extent will have the same effect.

Mr. HORAN. What I was getting at, Dr. Smith, is the possibility of having ready-made experiments available. Now cryolite, of course, is used in the reduction of alumina in our reduction mills by our aluminum companies. Would exposure to cryolite in that form and the handling of it give you a specimen that might be experimented on to find out the effect of cryolite on the individual?

Dr. SMITH. You mean not in the water?

Mr. HORAN. No; not in the water at all, just exposure in the air.

Dr. SMITH. No; I do not know anything about the absorption of fluorine through different paths.

Mr. HORAN. You would not know whether using it as a wet spray and exposure to it might affect the individual who was applying that spray?

Dr. SMITH. I am not in a position to say.

Mr. HORAN. That is all, Mr. Chairman.

The CHAIRMAN. Thank you, Doctor. I am sure you have made a definite contribution in coming here, and we appreciate your efforts.

Mr. KLEINFELD. Professor Howard Smith, please.

The CHAIRMAN. Give your name and address to the reporter.

Mr. SMITH. Howard V. Smith, University of Arizona, Tucson.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF HOWARD V. SMITH, ASSOCIATE AGRICULTURAL CHEMIST, UNIVERSITY OF ARIZONA, TUCSON, ARIZ.

Mr. KLEINFELD. Professor Smith, what degrees do you hold?

Mr. SMITH. B. S. and M. S. degrees.

Mr. KLEINFELD. Do you have a Ph. D. degree?

Mr. SMITH. No.

Mr. KLEINFELD. Where did you receive your two degrees, sir?

Mr. SMITH. University of Illinois.

Mr. KLEINFELD. What years?

Mr. SMITH. 1923 and 1924.

Mr. KLEINFELD. What have you done since your graduation? What has been your professional career since then?

Mr. SMITH. Experimentation at the Agricultural Experiment Station at the University of Arizona.

Mr. KLEINFELD. For how many years?

Mr. SMITH. I am in my twenty-eighth year now.

Mr. KLEINFELD. What position do you now hold with the University of Arizona?

Mr. SMITH. Associate agricultural chemist in the experiment station and associate agricultural chemist in the college.

Mr. KLEINFELD. Generally speaking, what do your duties consist of?

Mr. SMITH. In the experiment station they consist of research.

Mr. KLEINFELD. What is your special field of professional interest, Professor Smith?

Mr. SMITH. My special field of interest and training has been in soil, but for 10 years Dr. Smith and I engaged in fluoride studies together.

Mr. KLEINFELD. For about 10 years, you say?

Mr. SMITH. Yes; 10 to 12 years.

Mr. KLEINFELD. Please read your statement, sir.

Mr. SMITH. It has been proved that there is a correlation between the presence of optimum concentrations of fluorides in drinking water and the incidence of dental decay in the teeth of children who use this water during the time their permanent teeth are forming. This fact has led the United States Public Health Service, the American Water Works Association, the American Dental Association, the American Medical Association, the National Research Council, and others to approve fluoridation of public water supplies as a means of reducing caries in large segments of our population. It is my feeling that many of the proponents of fluoridating drinking water have not had a sufficiently wide experience with dental fluorosis or have not taken into account all of the variables involved in the problem to appraise the situation correctly.

As codiscoverer of the role which fluorine plays in dental fluorosis and as author or coauthor of many of more than 40 papers which have appeared from the University of Arizona on the subject, I want at the outset to say that I believe I have reason to say that there are many variables in this problem, and until more is known about them I am opposed to the fluoridation of water supplies.

I would like to present to you some hitherto unpublished data concerning the fluorine problem in Arizona. These data show very definitely that the concentration of fluorine recommended by the United States Public Health Service for maximum dental caries prevention at the minimum threshold level for protection against endemic fluorosis cannot be safely used in southern Arizona. Drinking waters containing 1.0 to 1.5 parts per million of fluorine or even less than this amount have been found to be associated with mottled teeth in varying degrees of severity in far too many of its users to justify the value of the protection afforded against tooth decay.

First, let us look at the situation in Tucson. The city water in Tucson is derived from two different sources. That supplied to the eastern part of the city has a fluorine content of only 0.3 part per million of fluorine while that applied to the south side has a fluorine content of 0.9 part per million of fluorine.

With the aid of John W. McInnes, D. D. S., examinations were conducted in order to obtain information regarding the teeth of the children who had lived in the same part of the city all of their lives and therefore used the same drinking water during the whole period of development of their permanent teeth. Children from the Mansfeld Junior High School on the east side and from the Roskruge Junior High School on the south were included in this examination for dental caries and mottled teeth. The children ranged in age from 12 to 15 years. We were impressed with a lower incidence of dental caries in the children in Roskruge who used water containing 0.9 part per million as compared with the children in Mansfeld who had access to water containing 0.3 part per million. Actually 42 percent of the children at Roskruge were free from caries whereas a lesser number, 26.7 percent, in Mansfeld had no cavities. If caries reduction alone was to be considered, it would be logical to conclude that fluoridation of water would be highly desirable and therefore to be advocated. However, a different story was unfolded when a comparison was made of the occurrence of mottled enamel on the teeth of these children.

More than a dozen years ago our laboratory reported that the drinking of water containing 0.9 part per million or more of fluorine by some Arizona children during the period of tooth development before eruption left a mark on the enamel. It was not surprising therefore that we found no children in Mansfeld showing dental fluorosis, while on the other hand 37 percent of those in Roskruge whose drinking water contained 0.9 part per million of fluorine, had mottled enamel varying in degree from very mild to moderate. These findings have been kept in my files for some years for they yielded no new disclosures. They did show that the presence of fluorine in drinking water afforded the teeth some protection against dental caries. Evidence of this sort from surveys of a much larger scale had been reported by the United States Public Health Service.

Due to the increasing emphasis placed upon the value of fluorine in drinking water as an inhibitor of dental caries we have since extended these studies to other communities in southern Arizona, the fluorine content of whose water supplies fall within the range 0.9 to 1.2 parts per million, concentrations which are considered by some to be advantageous to dental health. The teeth of children in Casa Grande, Florence, and San Xavier, each community being within 70 miles of Tucson and having a similar climate, have been examined. The fluorine concentration in the domestic waters in these communities are 1.0 to 1.3, and 1.0 parts per million respectively. Again, the findings have been compared with those resulting from the use of water containing only 0.3 part per million of fluorine.

Again our experience in caries reduction as a result of fluorine ingestion by the inhabitants of these communities has been similar to that of others who have been studying in this field. As the fluorine content of the water increases, in general the percentage of children having no cavities in their teeth becomes greater. This correlation between the fluorine content of waters and the reduction of caries was quite obvious in south Tucson, Case Grande, and Florence. The fluorine content in their water supplies of 0.9, 1.0, and 1.3 parts per million, respectively, was associated with an absence of tooth decay in 42, 54, and 65 percent of the children examined.

The same relationship in San Xavier, however, was not found. At San Xavier the water contained 1.0 part per million of fluorine, yet the percentage of children without caries was no lower than that found at Mansfeld where the water contained 0.3 part per million. Only 24 percent of the San Xavier children were free from caries. This divergence in relationship may perhaps be explained by a difference in racial, individual, or group response to fluorine as an inhibitor of dental caries. The children at San Xavier are Papago Indians. Their food habits are unique. They seldom if ever brush their teeth. They do not take cod liver oil, and seldom have dental care. Whatever the explanation it was evident that the dental caries health of the San Xavier children, drinking water containing 1.0 part per million of fluorine, was not superior to that of other children ingesting much less fluorine. On the other hand let us consider the other side of the situation. As stated before, the teeth of the school children in all of the communities were examined for dental fluorosis as well as dental caries. Again it has been noted that in the communities added to our original investigations, that is, San Xavier, Casa Grande, and Florence, a certain number had mottled teeth, the percentage of cases and the severity increasing with the increase in fluorine content of their water supply. It should be emphasized again at this point that the fluorine content of their water supplies lay within the concentration range advocated for fluoridation of public waters for mass control of dental caries. Ninety-four percent of the school children in Florence with a city water naturally containing 1.3 parts per million of fluorine had mottled teeth in varying degree of severity. Again, in Casa Grande almost half of the children drinking their city water naturally containing only slightly less than 1.0 part per million of fluorine had mottled teeth.

In both Florence and Casa Grande the advantage in dental caries protection gained by the presence of fluorine in the water supply was offset by disfiguring appearance of mottling of the enamel.

Again, in San Xavier, the Papago Indian school children drinking water containing only 1.0 part per million of fluorine showed no lower rate of dental caries incidence than children in east Tucson ingesting much less fluorine. Unfortunately also the teeth of almost 100 percent of these children were marred beyond repair. Again an individual difference within this race or group in response to the toxic action of fluorine was shown by the finding that 12 percent had very mild, 65 percent mild, and 23 percent moderate cases of mottled teeth.

It is evidence such as this which arouses my concern over the extended advocation by more and more groups of the fluoridation of public-water supplies. Much is still to be learned about variable factors which bring about a difference in response to fluorine both as a protector against dental decay and a toxic element interfering with normal development of the teeth and resulting disfigurement before mass control is undertaken.

Because of my close contact with the toxic effect of fluorine, a dental abnormality which is obviously unknown, ignored, or considered unimportant to the proponents of fluoridation of public-water supplies, I would like to mention some other points which constitute reasons for my objections to the fluoridation plan.

In the first place I do not believe that the minimal threshold for dental fluorosis is known for all parts of the United States. Nor can I agree with the proponents of fluoridation that it is acceptable for 10 to 12 percent of those ingesting fluorinated water to have mildly mottled teeth. There is surely an individual difference in what might be considered aesthetic or nonaesthetic. Undoubtedly the greater toxic reaction to fluorine concentrations in southern Arizona water supplies, that is, the higher fluorosis index, compared with northern cities with water supplies whose fluorine concentration is at the same level, can best be explained by differences in climatic conditions which influence the amount of water consumed.

Dr. MILLER. Let me ask a question right there, Mr. Chairman.

The CHAIRMAN. Dr. Miller.

Dr. MILLER. Did you find any dental caries in that group of children that had mottled teeth?

Mr. SMITH. Yes.

Dr. MILLER. In other words, if the mottled teeth was caused, as you think it might have been, by fluorine in the water, those children with the mottled teeth also had caries?

Mr. SMITH. A certain percentage of them; yes.

Dr. MILLER. Would you say the percentage was as large as those that did not have mottled teeth?

Mr. SMITH. We found it would be variable.

Dr. MILLER. Variable?

Mr. SMITH. Yes. The San Xavier Mission which teaches Indian children had a concentration of 1 part per million of fluorine. Only about 24 percent of the children did not have caries.

Dr. MILLER. All right.

Mr. SMITH. Dean has reported finding mottled enamel on teeth in Georgia produced by water containing 0.5 to 0.7 parts per million of fluorine of the same type as is produced in the vicinity of Chicago where the fluorine content is about 1.2 parts per million. The respective annual temperatures at the two locations are 68 and 49° F., respectively, which fact introduces again the climatic factor.

Undoubtedly water consumption is greater in warmer climatic zones than in cool ones.

In addition to temperatures it may be that relative humidity is a factor in determining water consumption. We are considering a plan to investigate the climatic factor in some detail in an attempt to set minimal threshold values for all parts of the United States on the basis of climatic zones as worked out by Thornthwaite. Thornthwaite has proposed two indexes to describe the climates of the world. They are the P-E index—precipitation effectiveness—and T-E ratio—thermal efficiency. When these ratios are integrated, climatic zones may be established. It is hoped that water consumption will be found to be a function of climatic conditions in each of these zones. If such appears to be the case, then threshold levels for fluorine could be established in each zone with relative ease.

Without a knowledge of threshold values for each climatic zone, fluoridation of waters may either be ineffective or may be dangerous.

Word from the Surgeon General's Office, United States Army, indicates the water requirement of man for temperate climate varies with activity, ranging from 900 cubic centimeters per day under a regime of light activity to 1 to 3 liters per day under conditions of normal activity. In a hot climate under conditions of moderate activity the daily intake is 2 gallons per day. With heavy exertion, the intake exceeds this amount. Dr. E. F. Adolph and associates, department of physiology, University of Rochester, in their monograph, Physiology of Man in the Desert, say:

> We find, for example, that a man must drink at least 5 and at the most 10 liters of fluid to meet his requirements when the mean daily temperature is 90° F. Men who are inactive and remain shaded most of the day will find 5 or 6 liters sufficient. Those who are moderately active in the sun will require about 7 or 8 liters, and men who work strenuously for long hours will need 9 or 10 liters on the same day. If the day is cooler, say, with a mean temperature of 80° F., the range of fluid needs will be from 3 to 7 liters, the exposed workingmen needing the most, the inactive men the least. These predictions coincide closely with the actual fluid turn-overs measured in different circumstances in the desert.

In actual practice those fortunate enough to have air conditioning, thus living under artificial climatic conditions, probably cannot be classified with population in the climatic zone in which they live.

Even though threshold concentrations for fluorine were established for all climatic zones in the United States the problem of individual susceptibility, unequal water intake due to exercise, racial differences, and variability in diet would still be with us.

We do not question the ability of the waterworks technician to inject a predetermined amount of fluoride into the water supply or to guarantee the amount present by means of frequent chemical analysis.

It may be also that if water is fluorinated to the point where it produces very mild mottled enamel on the teeth of 10 to 15 percent of the population and gives maximum protection against caries, no more serious damage may occur to any individual unless fluorine is ingested from some other source. This possibility is a reality in more instances than are known. For example, Cryolite, a fluorine-containing insecticide, is used on fruits and vegetables and is difficult to remove.

Ordinarily we do not expect to find high concentrations of fluorine naturally present in foodstuffs. Foods grown in Arizona soils by Vavich and Smith which had been treated with 400 to 1,600 parts per million of sodium and calcium fluorides took up only small amounts of

fluorine. Quite different results however were reported by Prince, et al., who grew plants in New Jersey soils. Buckwheat grown in soils containing 180 and 360 parts per million of fluorine contained 1,170 and 1,280 parts per million of this element respectively. Similar work conducted at Beltsville, Md., by Annie M. Hurd-Karrer, of the United States Department of Agriculture, shows that such crops as collard and buckwheat take up as much as 9,900 parts per million of fluorine when 102 parts per million of fluorine was added to the soil in which they were grown. This great difference in uptake of fluorine is explained on the line content of the soils and their pH. There is little tendency for plants grown on alkaline calcareous soils to absorb fluorine. Liming acid soils decreased the fluorine content of plants grown on them.

Thus it is that the fluorine content of certain foodstuff may vary widely and therefore the amount consumed in addition to that obtained from fluoridated waters will be impossible to predict.

It has also been noted that healthy individuals excrete fluorine in concentrations near the concentration ingested. If a kidney impairment prevents the proper excretion of this element its retention may become serious.

The topical application of fluorine to teeth has been practiced for several years, both on an experimental and practical basis. Caries reduction by this method is reported to be about the same as from the use of water containing added fluorine. When topical application of fluorine is used none of the chemical is ingested. Mass application however is not as easily achieved as where public water supplies are fluoridated. If caries incidence can be adequately reduced by other means the practice of fluorinating water loses some of its attractiveness, especially when such practices as the use of ammoniated dentifrices, good diets, antibiotics, chemicals of various sorts, et cetera, can give good results. Smallpox and other diseases have been controlled by individual vaccination and it is possible also to treat caries on an individual basis without danger to the individual.

In conclusion I would like to reemphasize the following:

1. Minimal threshold levels for fluorine have not been established in all climatic zones of the United States so safe fluoride concentrations in each zone are not known.

2. Fluorine from vegetables and fruits dusted with fluorides, baby foods, and foods grown on acid soils which are high in fluorine may be additive to that already in the water and cause a greater prevalence of mottled enamel of a more serious type.

3. Individual tolerance to fluorine and differences in the amount of water consumed as a result of environment or occupation have a bearing on the amount of water of a given fluorine concentration which can safely be ingested and therefore make it difficult to establish optimum levels for fluoridation of public water supplies.

4. The safest procedure, it seems to me, for reducing caries in teeth by the use of fluorine is topical application to children's teeth in schools as part of the State's public health program.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Professor Smith, when did you say you began to study the effects of fluorine in water?

Mr. SMITH. In 1930.

Mr. KLEINFELD. What caused you to begin this study?

Mr. SMITH. Dr. Margaret Smith in her nutritional experimentation had indicated that she thought fluorine might be the offender, and needing more hands as a chemist, we collaborated. That is how I got into it.

Mr. KLEINFELD. Am I right in concluding, from your statement, that you believe there are several variable factors which may influence, for example, the degree of mottling in the teeth of people who drink water with different concentrations of fluorine or sodium fluoride?

Mr. SMITH. Yes, I do.

Mr. KLEINFELD. What would those factors be—mostly ingestion of water?

Mr. SMITH. Possibly, yes.

Mr. KLEINFELD. What else?

Mr. SMITH. Possibly food containing greater or lesser amounts of fluorine; muscular activity.

Mr. KLEINFELD. Let's assume a city like the District of Columbia wishes to fluoridate its drinking water supply. What factors in your opinion should be taken into consideration in determining, let's say, to put 1 part per million of sodium fluoride in the drinking water? Would you be willing to rely on the fact that no untoward consequences have occurred in some other cities in a different part of the country which have been using for a number of years water artificially containing 1 part per million of sodium fluoride?

Mr. SMITH. There are many reports in the literature of two cities having the same fluorine concentration in the drinking water having different caries and mottling experience in the teeth.

Mr. KLEINFELD. If you had the say, Professor Smith, in determining whether or not to fluoridate the public drinking water of a large city like Washington, D. C., what would you have investigated before doing so, or would you do so at all?

Mr. SMITH. I wouldn't do so at all.

Mr. KLEINFELD. Again, why wouldn't you do so?

Mr. SMITH. Because it has been shown that 10 to 12 percent of the children who ingest recommended concentrations of fluorine in drinking water in this climatic zone will be expected to have mottled teeth.

Mr. KLEINFELD. In the climatic zone which includes Washington, D. C.?

Mr. SMITH. The closest one to Washington, D. C., would be Chicago. I suppose Washington, D. C., is a little warmer than Chicago, and we might expect a little more ingestion of water.

Dr. MILLER. Mr. Counsel, at that point—those children with mottled teeth, do they also sometimes have caries?

Mr. SMITH. They do, very definitely.

Dr. MILLER. So the use of fluorine to prevent caries is not as absolute as immunizing the child against diphtheria or vaccination against smallpox. If you do that to the child, you can say absolutely that he will not have smallpox, if the vaccination is properly done.

Here they say using fluorine in the water to prevent caries in the teeth—and if I understand you correctly, they sometimes produce mottled teeth, probably where the looks are not too bad, but they have dental caries, which fluorine did not prevent. That is what you are saying?

Mr. SMITH. Yes. No one has claimed a perfect cure or prevention of caries.

Dr. MILLER. Do children get mottled teeth when they have fluorine applied topically by the dentist?

Mr. SMITH. No; they do not.

Dr. MILLER. Only when they ingest it?

Mr. SMITH. Yes.

Dr. MILLER. That is all.

The CHAIRMAN. I do not want to interfere, but I have a boy who has had that treatment for some years by a dentist who has been an advocate of it, and he gets caries in his teeth. I mean that is just one example.

Mr. SMITH. That is true. The proponents of either method do not claim complete protection—30 percent, 40 percent, and the greatest about 60 percent.

The CHAIRMAN. When you say 30 or 40 percent you mean?

Mr. SMITH. Reduction. 30 percent reduction—40 and 50.

The CHAIRMAN. Dr. Miller.

Dr. MILLER. Although even the topical application also have caries?

Mr. SMITH. Yes; it is not a perfect cure.

Dr. MILLER. A reduction of 30 or 40 percent?

Mr. SMITH. Yes.

Mr. KLEINFELD. Mr. Smith, I believe you testified, as most of the witnesses here have, that there is a reduction in the incidence of dental caries when water is fluoridated. If that is a fact, and most people so agree, the thing that you object to most, apparently, is this mottling. What is so bad about mottling?

Mr. SMITH. May I answer that by asking a question?

Mr. KLEINFELD. Yes, sir.

Mr. SMITH. Would you like to have mottled enamel?

Mr. KLEINFELD. I wouldn't; no.

Mr. SMITH. That is what these other people, some of them, think.

Mr. KLEINFELD. When you say mottling, Professor Smith, there are various degrees of mottling, as you and Dr. Smith, the preceding witness, have pointed out.

Let's take this very mild mottling. Are you familiar with that category?

Mr. SMITH. Yes.

Mr. KLEINFELD. What would that amount to? Would that be readily discernable by a layman such as myself, for example?

Mr. SMITH. I think so.

Dr. MILLER. It is like having a little bit of a cross eye? [Laughter.]

Mr. SMITH. There are white flecks over the teeth, which to some, particularly the person who is afflicted, is not aesthetic.

Mr. KLEINFELD. Have you observed considerable numbers of persons who have mottled teeth?

Mr. SMITH. I have.

Mr. KLEINFELD. In the various categories such as mentioned here—mild and very mild?

Mr. SMITH. Yes.

Mr. KLEINFELD. Do you know how those people react to this mottling, even the very mild mottling?

Mr. SMITH. The very mildest probably do not object very seriously, but in our experience, if a water contains 1.3 parts per million of fluorine, the mottling is mild, but it is certainly very noticeable to the lay person.

Mr. KLEINFELD. I think you said that, in an area such as Chicago, if you added about 1 part per million of fluorine to the drinking water you might expect 10 to 12 percent of the children to have some mottling?

Mr. SMITH. I think that is what is reported in the literature.

Mr. KLEINFELD. Do you know what that mottling would consist of? Would that 10 to 12 percent be mild, very mild, or what?

Mr. SMITH. It would be mild, and a little, perhaps a little greater degree of mottling than the mild in a certain number of individuals. There is a variation in individual susceptibility.

Mr. KLEINFELD. But you feel that a number of that percentage of children there would have mottling which would be unaesthetic and readily discernible by the ordinary layman?

Mr. SMITH. Yes; I do.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Dr. Miller?

Dr. MILLER. In the case of the use of fluorine, Doctor, whether it is used topically or taken into the water, is there any difference in the amount of caries that children might have?

Mr. SMITH. I think if we are conservative, we will say that the effect is about the same in either case.

Dr. MILLER. You mean about the same in either case?

Mr. SMITH. The proponents of fluoridation are claiming a little higher caries reduction than the topical application proponents.

Dr. MILLER. Do you know what experiments were carried on by the United States Public Health Service, the American Medical Association, and the Dental Association now advocating the use of fluorine as a mass medication before they made their recommendations?

Mr. SMITH. I am familiar with quite a few of them; yes.

Dr. MILLER. Were they complete and satisfactory?

Mr. SMITH. The experiments at Newburgh, N. Y., were planned for 10 years, and they are in the seventh year now and have not been carried to completion.

Dr. MILLER. Is that not under the direction of the United States Public Health Service?

Mr. SMITH. I am not sure whether it is or not.

Dr. MILLER. And you think those ought to be carried on to completion before any conclusions are reached?

Mr. SMITH. Yes.

Dr. MILLER. What would you say this committee ought to recommend relative to fluoridation of water?

Mr. SMITH. My personal feeling is that fluorine ingestion is dangerous and that it should not be carried out.

Dr. MILLER. You realize a lot of people do not agree with you?

Mr. SMITH. I realize I am in the minority.

Dr. MILLER. That is all I have.

The CHAIRMAN. Mr. Horan?

Mr. HORAN. We are dealing, of course, with a very useful chemical here in fluorine. You recognize that?

Mr. SMITH. I do.

Mr. HORAN. It is used very widely and to the widespread benefit of mankind, so it is a matter of us finding out how to use it, is it not?

Mr. SMITH. Yes.

Mr. HORAN. Under proper conditions?

Mr. SMITH. Yes.

Mr. HORAN. Have you had any experience of observing the effect of fluorine in spraying fruits or vegetables?

Mr. SMITH. Not the mechanics of it; no, I have not.

Mr. HORAN. I, personally, have sprayed with fluorines, and I think it would be impossible not to ingest some of it if you work all day in the hot sun and use a certain dosage of Cryolite or synthetic cryocide in your spray dope.

Mr. SMITH. Yes.

Mr. HORAN. Would it be reasonable to assume you might ingest a little that way?

Mr. SMITH. Yes.

Mr. HORAN. You are aware, of course, that we are conducting studies under the supervision of the Public Health Service on the effect of insecticides on human beings in the State of Washington?

Mr. SMITH. Well, I am aware of the fact that the Food and Drug Administration has set a tolerance of 7 parts per million for fruit.

Mr. HORAN. Yes. That was several years ago. We just started examination to try to find out what the effect is on the individual through the use or being in the proximity of Cryolite or synthetic cryocides, either in applying them or mixing them. You are not familiar, though, with that work?

Mr. SMITH. No; I am not familiar with it.

Mr. HORAN. I think you would be interested in that, because you have raised some very good questions here to me. I cannot understand, though, for the life of me, Mr. Chairman, how this collard and buckwheat took up 9,900 parts per million from soil that didn't have that much in it. What is your ratio there?

Mr. SMITH. It was added as an amendment to the soil, and the soil was very acid.

Since this paper was written, I have talked with one of the men connected with the above tests. He said that ordinarily not that much is taken up from agricultural soils.

Mr. HORAN. Have any experiments been conducted using collard or buckwheat and feeding it to rats to your knowledge to see the effect?

Mr. SMITH. I don't believe the Beltsville or New Jersey experiments were carried into feeding experiments. Certainly if it was there in that concentration, it would affect an experimental animal very seriously.

Mr. HORAN. You feel that sort of research ought to be conducted?

Mr. SMITH. Yes.

Mr. HORAN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Dr. Smith.

The committee will recess now until Thursday morning at 10.

(Whereupon, at 11:55 a. m., the committee recessed to reconvene at 10 a. m., on Thursday, February 28, 1952.)

CHEMICALS IN FOODS AND COSMETICS

THURSDAY, FEBRUARY 28, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess., continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.), at 10 a. m., in room 445, Old House Office Building, Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney of New York, Jones of Missouri, Abernethy of Mississippi, Miller of Nebraska, and Horan of Washington.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will come to order.

Mr. Kleinfeld.

Mr. KLEINFELD. Is Dr. Forsyth here, or Dr. Knutson? Is anybody here for the Public Health Service?

A VOICE. There is going to be a delegation here and they should be here any minute.

(Interval of several minutes.)

The CHAIRMAN. Dr. Knutson, are you going to testify or is Dr Forsyth or someone else?

Dr. KNUTSON. Dr. Forsyth and Dr. Dean.

Dr. MILLER. I suggest to the chairman that we have Dr. Forsyth and Dr. Dean up here at the table.

Dr. KNUTSON. I am not scheduled to testify. Dr. Forsyth will return in a minute, sir, and lead off.

Dr. MILLER. Would you mind submitting to some questions here at the table with the rest of them? I have a number of your publications here and I want to ask you a few questions about them, and you will be in position to answer some of the questions.

Dr. KNUTSON. Surely, I will be glad to.

The CHAIRMAN. You have been sworn in, have you not?

Dr. KNUTSON. Yes.

The CHAIRMAN. Dr. Knutson is recalled.

TESTIMONY OF JOHN W. KNUTSON, D. D. S.—Recalled

Dr. MILLER. Dr. Knutson, somebody left at my office, I believe you or someone else, a bunch of publications which were very interesting reading, on the question of fluorine in drinking water.

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There were some questions in my mind on the use of fluorine, and I wanted to ask some experts, and you are an expert and have been dealing and probing into the use of fluorine in drinking water.

As a physician, I have always sort of approved and thought it a good thing. In fact, I introduced a bill in Congress that the District of Columbia add fluorine to the water.

In the last few days we have had some testimony from experts, also in the field, and experimenting 10, 12, 13 years, and longer, and some of their findings have disturbed me a little bit. I am sort of between and betwixt as to what we should advocate.

Do you know Dr. Francis A. Arnold, Jr., D. D. S., of Bethesda, Md.?

Dr. KNUTSON. He is one of my colleagues and he is here this morning.

Dr. MILLER. Maybe I should ask Dr. Arnold. I do not know.

But Fluorine in Drinking Water: Its Effect on Dental Caries, as published in the Journal of the American Dental Association, volume 36, pages 28–36, January 1948, is an article by Dr. Arnold on fluorine in drinking water.

I notice he says in his summary on this subject on page 36, and I quote:

> Presumptive evidence points to fluorine as the active inhibitory agent and suggests the possibility of adding controlled amounts of fluorine to water supplies as a practical method of preventing or inhibiting caries.
>
> Studies of such a procedure are now in progress, but final evaluation must be deferred during the time required for teeth to develop and erupt under this changed environment. At present it is deemed advisable to await the results of these research projects before an unqualified recommendation for mass fluoridation of water supplies is made.

Would you or Dr. Arnold tell the committee what experiments have been carried on that have now apparently brought you to the position of recommending the use of fluorine in water, because he says here, and I quote again:

> At present it is deemed advisable to await the results of these research projects before an unqualified recommendation for mass fluoridation of water supplies is made.

Dr. KNUTSON. I should be very glad to comment on that, Dr. Miller, but since Dr. Arnold, the author, is right here, I think he should answer.

The CHAIRMAN. Dr. Arnold. Give the reporter your name and address.

Dr. ARNOLD. Francis A. Arnold, Jr., National Institutes of Health, Bethesda, Md.

(The oath was administered by the chairman.)

TESTIMONY OF FRANCIS A. ARNOLD, JR., D. D. S., NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD.

Dr. MILLER. You heard the reading of the summary in this publication of Fluorine in Drinking Water: Its Effect on Dental Caries?

Dr. ARNOLD. Yes, sir.

Dr. MILLER. Would you care to comment as to what projects or what experiments have been carried on now that have caused the Public Health Service to recommend mass fluoridation of water supplies?

Dr. ARNOLD. I will be very happy to comment on it, Mr. Congressman. As you know, the date of the issue of that publication——

Dr. MILLER. January 1948.

Dr. ARNOLD. Is January 1948. I am sure the committee realizes that the paper was written well before publication date.

I would also like to point out that in 1948 we still had in progress the studies at Grand Rapids, Mich., the studies at Newburgh and Kingston, the studies at Brantford, Ontario, the study just started in Evanston, Ill., at that time, and the other fluoridation studies in North Carolina had started about that time.

The study in Grand Rapids, with which I am definitely more familiar, had been in progress about 3 years by 1948. The study started in January 1945. The results that we had obtained when that paper was written, such as on the Grand Rapids study, and the results from the Newburgh study and the Brantford study had not been published, nor had these studies gone long enough to obtain statistically significant results when that statement was made. It is based on that fact.

Dr. MILLER. Well, I have another publication by Francis A. Arnold, Jr., Research in Dentistry for Children.

I believe this was published in Tufts College Dental School Magazine. I note in the summary—I read the article and this is in May 1951, after you made certain findings on caries in children—this quotation:

> In the past 2 or 3 years, increased funds have been made available directly to the National Institute of Dental Research and to promising individuals in dental schools and research institutions in the form of research grant-in-aid. It is too early to evaluate the effect of this increased research activity on the improvement of the dental health of children in the United States.
>
> In our efforts to train better dentists and instructors, the search for new knowledge must not cease. Only through constant research can children's dentistry progress and provide better service for children.

The thing that intrigued me was in this statement of May 1951, you said:

> It is too early to evaluate the effect of this increased research activity on the improvement of the dental health of children in these United States.

Now that covers the item of fluoridation of water, too, I believe, as other subjects in the article. You think in May 1951, it was still too early to evaluate research findings.

Now, I believe Congress made available about a million dollars 3 years ago for general research. I voted for it, I thought it was a fine thing. But I am wondering whether someone in the Public Health is not getting a little enthusiastic about pushing forward.

A gentleman here had his hand up and may want to answer, Mr. Chairman.

The CHAIRMAN. If he can answer later, we have this witness first.

Dr. MILLER. I would like the author to answer this question. "It is too early"—1951—"to evaluate the effect of this increased research activity on the improvement of the dental health of children in these United States."

Now, that was after Congress appropriated a million dollars the year before, 1949, for research particularly in fluoridation of water. I wonder if you have any comment on that.

Dr. ARNOLD. Mr. Congressman, yes, I do have a comment on that.

I think the article that you are referring to refers to research done under our research grants program. I mean that includes all types of dental research.

Dr. MILLER. Yes, I think that is true, Doctor.

Dr. ARNOLD. Our research grants program got started at about $221,000, Mr. Congressman, in 1948.

Dr. MILLER. That is right.

Dr. ARNOLD. And what I was referring to there was that this was a step forward, and we were very glad to make that step.

Dr. MILLER. I think that is right.

Dr. ARNOLD. I was referring to various types of research that need to be done.

Dr. MILLER. I have another article here by Francis A. Arnold, Jr., D. D. S., Fluoride Therapy for the Control of Dental Caries, reprinted in the Journal of the American Dental Association, October 1948. Now that was after January 1948, some 8 months later, and in the summary there you say relative to fluorine:

> At present there is no acceptably controlled scientific evidence in an adequate number of observations with which to evaluate the supplemental feeding of fluoride for caries control.

Of course now, that was in October 1948. What has developed since then in light of the 1951 statement that brings you to the position, or the Public Health Service to the position, that it is a sort of a must, as one of the articles state here, for medication of caries through fluoridation of water—that is a must if you are going to prevent caries in children? What has happened since then?

Dr. ARNOLD. Mr. Congressman, if I am not mistaken, in the article to which you are referring, I was discussing the possibilities of supplementing diets with fluorides.

Now I would like to take a moment to explain the difference of what we are speaking of in terms of supplementing diets, rather than putting fluorides in water supplies.

I did start a small study back in 1942, and started it on my own family, because I was convinced as early as 1942 that fluorides were beneficial to dental health.

I did start feeding and supplementing the diets of my children and of many people around the institute, professional people, who were able to recognize the problem and work on the experiment of adding fluorides to their children's diets. It is a case of adding a known amount of fluoride daily, supplementing the diet of a child daily with a known amount of fluorides.

The doses that we are using are based on the same amount of fluoride that one would assume to be ingested in an area where the water supply contained about 1 part per million of fluorine.

Dr. MILLER. I want to come to that thought in just a little while, about fluorine in foods.

First, I would like to ask you relative to fluoride in water—I think you are able to answer it—I have a little publication here, Production of Mottled Enamel Halted by Change in Common Water Supply, by H. Trendley Dean and Frederick S. McKay. In it is this statement:

> In the United States at present there are about 375 known areas, divided among 26 States where mottled enamel of varying degrees of severity is found. This large number of areas made available for study various communities whose

common water supply contained fluorides in different concentrations. This, in turn, permitted detailed quantitative study of concomitant variations.

And in the summary:

With the report on the results obtained in three endemic areas, showing that the production of mottled enamel has actually been stopped by the mere change in the water supply from one containing concentrations of fluoride toxic to calcifying dental enamel to one practically free of fluoride, the most conclusive and direct proof that fluoride in the domestic water is the primary cause of human mottled enamel, has been presented.

This paper was published June 1939, in the American Journal of Public Health, volume 29, No. 6.

What are you doing about taking fluorine out of water when there is more fluorine in than is apparently needed?

Dr. ARNOLD. Mr. Chairman and Mr. Congressmen, Dr. Forsyth is here and Dr. Dean is here this morning.

I think I would like to transfer the question, if you don't mind, to Dr. Forsyth and Dr. Dean. I will be available and glad to answer any questions.

The CHAIRMAN. Is there anyone who can answer the questions asked by Dr. Miller—anyone from Public Health?

Dr. FORSYTH. Dr. Dean is the Director of the National Institute of Dental Research, National Institute of Health.

Dr. ARNOLD. He wrote those articles and has been working in the field.

The CHAIRMAN. You, yourself, Doctor, have not personally supervised any survey on mottled teeth or the effect of fluorine on public health?

Dr. ARNOLD. Yes, sir, Mr. Chairman, I started working in the field of fluorides in 1937 when I was detailed to the National Institute of Health and have worked with Dr. Dean, my senior officer, since that time, and have surveyed many areas for fluorine present in the water. I would——

The CHAIRMAN. Just a moment. On Tuesday, Dr. Margaret Smith came here. She is a nutritionist, and I believe her husband, Professor Smith, is a chemist. Dr. Smith testified she had made a survey from 1930 until 1934 in Arizona on mottled teeth. She told of her experience and what she found, and later Professor Smith also told of his experience and the effects that fluorine in water had on teeth. These people have done extensive work in this field. They have realized they are subject to a certain amount of criticism, and they were willing to come here and testify before this committee as to what they believed and what they found.

Have you read their testimony?

Dr. ARNOLD. No, sir; I have not.

The CHAIRMAN. All right.

Dr. KNUTSON. Mr. Chairman, my understanding is we came here this morning prepared to present a brief supplemental statement, and——

The CHAIRMAN. You will be given that opportunity. Dr. Miller requested an opportunity to ask questions. Now I believe Dr. Dean said he could answer those questions.

Dr. MILLER. I prefer to wait until I ask two more questions of Dr. Arnold. I will be through then with him.

I have another publication of yours, Dr. Arnold, about the possibilities of reducing dental caries by fluoride ingestion. It is a very interesting article. I compliment you on it. It is well prepared. But the statement that disturbed me a little, again was in the summary, and it is obviously impossible to put the whole article in the record. But in your summary, and I quote this at page 107:

> Little, if any, effect can be expected in people who are more than 5 or 6 years of age when such fluorine therapy is instituted.

In other words, it is your conclusion that fluorine does not help the youngsters who are more than 5 or 6 years of age. Are you still of that conclusion as in that article of—I do not see the date on it, but you are probably familiar with it.

Dr. ARNOLD. I think, Mr. Congressman, that article came out in 1944 but I am not positive of that.

Dr. MILLER. It came out when?

Dr. ARNOLD. 1944.

I would like to point out for the record and for you, Mr. Congressman and Mr. Chairman, that I am wholeheartedly in support of fluoridation of water supplies for caries control. I have worked in this field, as I said, since 1937. I was convinced as early as 1942 that the addition of fluorides to the diet of individuals would increase or benefit their dental health: It would reduce the amount of dental caries.

The reason the statements have been made in that article that little benefit may be expected, I think they are the words I used, for children over 5 or 6 years of age, is because of the fact in our epidemiological studies, Dr. Dean and myself and others in the Public Health Service had been working with children who were born and reared in natural fluoride areas. They had formed their teeth on fluoridated waters, they had gone through gestation on fluoride water, they had gone through early childhood on fluoride water.

We knew at that time in terms of the study at Bauxite, Ark., on the change of water supplies that the individuals at Bauxite who formed their teeth on the fluoride waters, and then the fluoride water was removed, that they still retained the benefit. So we assumed at that time that the benefits to be gained from fluorine in the water supply was a benefit gained in the formative period of the tooth. The 5 or 6 years it referred to there, generally speaking, covers the main portion of the formative period of the permanent teeth.

We did not believe at that time that there was any benefit to be promised anybody or to be expected, scientifically speaking, in teeth that were already formed or already erupted in the mouth.

Since that time, I would also like to point out for the record, in our studies like Grand Rapids and the studies at Newburgh and the studies at Brantford, they are showing some benefit being gained by individuals who are more than 5 or 6 years of age, but we did not expect that when we started the study. We expected they would have little, if any, benefit, and we certainly wanted to be very cautious and not promise anybody any benefit if their teeth were already formed.

Dr. MILLER. I think that is right, Doctor.

I have another publication here, Evaluation of Effectiveness of Caries Control Measures of Ingested Fluorides in Water, Food, Bone Meal, and Proprietary Preparations, written by Dr. Francis A.

Arnold, Jr., D. D. S., Bethesda, Md. printed, I believe, in April 1948. Your opening statement is this:

> I do not think that it is possible this morning for us to talk on the evaluation of fluorides in dental caries control as far as water supply, food and other preparations are concerned, because we do not have sufficient data with which to evaluate the use of such materials.

Are you still of that same opinion or have you changed your mind since then?

Dr. ARNOLD. Very definitely, Mr. Congressman, I have changed my mind, and I feel very definitely we do have the data with which to proceed on putting fluorine in drinking water.

Dr. MILLER. We are making progress then.

I notice one of the questions at that time was a question by Dr. Wallace D. Armstrong, who said:

> I was troubled by the same thought that Dr. Stearns brought up, but I was going to discuss it in private with Dr. Arnold, since I didn't think it would be a point of general interest to the group. We have been able to show that by feeding drinking water containing 20 parts per million of fluorine to rats the fluorine content of the skeletal system increases 10- or 20-fold. I think we should repeat this experiment and analyze the whole skeleton so as to see what fraction of the administered dose was retained in this manner. As a matter of fact, in my experience, the determination of fluorine in urine and in feces is extremely difficult, if not impossible. The results are usually on the high side, more fluoride being found in the urine to which a definite amount of sodium fluoride has been added than is actually present. So I have never quite been able to understand the results that McClure obtained which indicate the excretion of nearly 100 percent of the administered dose. We should also consider the fact that the subjects were receiving fluoride in materials other than in the water, so that the apparent positive 100 percent excretion may not amount to that.
>
> It would be interesting, I think, to obtain some bone from an autopsy specimen in the fluoride areas, and I dare say that you would find the content of those bones to be much higher than in nonfluoride areas.

Have you found that to be the truth, or have you carried on those experiments?

Dr. ARNOLD. I have not carried on any experiments in that line, Mr. Congressman, but there have been experiments carried on by Dr. Hodge at Rochester, where they have analyzed bones from autopsies in fluoride areas, and there has been some increase in the fluoride content of the bones. That would be expected. I mean bone is a storehouse for calcium materials, and it would act in terms of an area in the body where one would naturally expect fluorine to be present.

There would be some increase expected and there is some increase in fluorine in the bones in these areas, but it is not an increase that becomes a pathological condition of the bones.

Dr. MILLER. In using fluoride as recommended by the Public Health Service, what percentage of caries do you prevent?

Dr. ARNOLD. Our studies at Grand Rapids show a 65-percent reduction in dental caries in those children now who were born and reared in Grand Rapids. That is the present 5- and 6-year-old children in Grand Rapids.

Dr. MILLER. Are you still carrying on some experiments of the use of fluorine in water.

Dr. ARNOLD. Grand Rapids is still proceeding; yes, sir.

Dr. MILLER. And are other scientists carrying on some experiments?

Dr. ARNOLD. Yes, sir. The studies in Newburgh are still proceeding and also Evanston.

Dr. MILLER. Do you know how long before the studies in Newburgh will be completed? They set up a 10-year program, did they not? I will help you with that.

Dr. ARNOLD. Yes, sir; Mr. Congressman. I do not mind speaking of that. We set up a 10-year program in Grand Rapids, sir.

Dr. MILLER. Yes.

Dr. ARNOLD. As I began this statement, we did not expect and really could not promise anybody any benefits in Grand Rapids until we observed a group of children who had erupted their permanent teeth—those teeth start coming in at 6 years of age—and who had been exposed to the caries attack forces present in the community; then to analyze how those teeth would resist caries.

It is surprising to us to find that we have not had to wait quite that long to show very definite beneficial effects. That is something we did not expect when we started.

Dr. MILLER. There are some things yet to be done as far as experimental work is concerned?

Dr. ARNOLD. There are things to be done, yes sir, and I am sure in terms of research there is always research to be done.

Dr. MILLER. And there are some answers you have not found to questions relative to the effect of fluorine upon the span of life, upon other functions of the body, metabolic and so forth.

Dr. ARNOLD. I am sure the committee appreciates that the studies in Grand Rapids, Newburgh, and so forth, have not proceeded for the span of anyone's life, but we do have data in natural fluoride areas where people have lived a complete span of life.

Dr. MILLER. Do you think that the public interest is best served by a more cautious attitude about the use of fluorides in water until we complete these experiments?

Dr. ARNOLD. No, sir. I think the public interest is best served definitely, Mr. Congressman, by endorsing and having the public start putting fluorine in their water supply today, because each year they wait there is a new generation of people that are getting less and less protection. And the results from Grand Rapids, Newburgh, Evanston, Brantford, point to that very clearly.

Dr. MILLER. In your opinion, if you had fluorides in your food, would you get about the same result as if you had them in your drinking water?

Dr. ARNOLD. In my opinion, yes, sir, there is no difference between them.

Dr. MILLER. No difference whether it is in the drinking water or cooked in the food.

You are familiar with Fluorine in Foods—Survey of Recent Data, by F. J. McClure, August 1949, in which he lists several hundred foods, outlining the amount of fluorine in these foods. Some of them run far over the 1 part per million.

If you and I had a balanced diet, our food would all contain, I guess, pretty close to 1 part or 1½ parts per million. That is if we had no drinking water at all.

Are you familiar with this study of Fluorine in Foods?

Dr. ARNOLD. Yes, sir; and Mr. Congressman, I would like to point out that unfortunately Dr. McClure is ill today. We had planned to have him here. We have a statement from Dr. McClure which Dr. Zipkin, his assistant, would be glad to read to you.

Dr. MILLER. If you have fluorides in food and start adding more in water, what is the danger point? There are 375 cities somewhere with more than they ought to have, and now you are going to put fluoride in their water.

Dr. ARNOLD. No, sir; not where there is more than one part per million.

Dr. MILLER. Where are we going to know to stop so you won't have mottled teeth? You are talking about putting fluorides in all water of the country in your statement.

Dr. ARNOLD. For the record, sir, it is in all the areas where they do not have optimum level.

Mr. ABERNETHY. Would you yield, Dr. Miller?

Dr. MILLER. Yes.

Mr. ABERNETHY. You are holding in your hand a pamphlet which I assume was issued over the name of a doctor to whom you refer; is that correct?

Dr. MILLER. The Federal Security Agency.

Mr. ABERNETHY. And the witness in the well has stated that he has a statement. I wanted to know if there is any difference in the two statements—in the one which Dr. Miller holds in his hands, and the statement to which you refer.

Dr. ARNOLD. No, sir. The statement to which I referred was that article written by Dr. McClure.

Mr. ABERNETHY. What did you say about it?

Dr. ARNOLD. Dr. McClure, I say, has a statement concerning the research that has been done on ingestion of fluorides from food, from water, and so forth; that if the committee prefers, we would be glad to have Dr. McClure's statement read.

Mr. ABERNETHY. I came in late and——

Dr. ARNOLD. In order to answer the questions Dr. Miller has brought up.

Mr. ABERNETHY. I was detained and came in late. Are you of Public Health?

Dr. ARNOLD. Yes, sir.

Mr. ABERNETHY. I have been here during the testimony offered by several of these doctors. I have been interested in their testimony. One of them was Dr. Alfred Taylor. Do you know of any work he has done in this field of experimental work?

Dr. ARNOLD. Yes, sir. I am not entirely familiar with Dr. Taylor's studies. But, again, Mr. Chairman, we have Dr. Forsyth here with a statement in that regard. We have Dr. Andervont from the National Cancer Institute, who is here to testify and has been down in Texas and looked over Dr. Taylor's work. So I think he is far better qualified to talk on it than I am.

Mr. HORAN. Might I ask this witness a question?

The CHAIRMAN. Mr. Horan.

Mr. HORAN. These, Dr. Arnold, are by nature of general questions I would like to have an answer to.

Now fluoride is not a new chemical by any means. We have years of experience in its use on the part of those who mine it, we have years of experience on the part of those who have used it experimentally and commercially in spray dopes. We have years of experience in its use as a fluoride bath in the development of alumina into aluminum.

I was trying to get from the witnesses of prior date if any findings had been found in those fields. Certainly, if there were any proper suspicion, Public Health would be called in to investigate, I would think.

Do you have any experience as to the effect on the human being when he is in direct and continuous and, probably in some cases, overwhelming contact with fluorides, either cryolite or in its synthetic form?

Dr. ARNOLD. Mr. Congressman, Mr. Chairman, I would again like to point out, sir, that Dr. Dean, who has more experience in this field than anybody I know of in this country, is in the room, has studied in cryolite areas. I have been there, too, but I think he is much better qualified.

Mr. HORAN. That is all I wanted, and I do want that an open question.

The CHAIRMAN. One more question by Dr. Miller.

Dr. MILLER. Do you not think this committee, who must make some recommendations on fluorine, would be wise to say to municipalities that contemplate the use of fluorine in their water, that they should have all the pros and cons and understand that experiments now in progress have not been completed as to what the ultimate effect might be upon the human being? Do you not think we ought to be fair? In some places they have more fluorine than they need.

Dr. ARNOLD. Mr. Congressman, I do not think I can quite say "Yes" to your question. I heard Dr. Blayney's testimony the other day. I know Dr. Blayney very well and I know his stand. I am sure that all communities should be advised and the problem should be discussed, and I am sure it has been in any community we have been into. I think our Public Health Service is trying to get a program going where we would give technical advice to all the communities.

Dr. MILLER. I am sure that is true.

I have one other statement here on the subject of Methods of Removing Fluorides From Water, by F. J. Maier, sanitary engineer, Dental Public Health Section, State Relations Division, United States Public Health Service, Washington, D. C. Do you know the gentleman?

Dr. ARNOLD. Yes, sir.

Dr. MILLER. Is he in the room, too?

Dr. ARNOLD. He is also in the room.

Dr. MILLER. I am glad to have him here. I would like to ask him after a while concerning his summary and conclusions on too much fluorides in the water.

He says in the summary and conclusions of this statement of his:

> More than a million persons in over 500 communities in the United States are now using public water supplies containing in excess of 1.5 parts per million fluorides. The disfiguring dental condition which is caused by the use of such waters for drinking purposes can be prevented in future populations of these communities by removing the excess fluorides from the communal water supplies.

He says later:

> Until this information is available, endemic fluorosis will continue to be a dental hazard to a large population in many communities in this country.

Do you think that is a fair statement?

Dr. ARNOLD. Yes, sir, Mr. Chairman. I am sure that we are well aware of the hazards of excess fluorides.

Dr. MILLER. What are you doing about trying to remove excess fluorides?

Dr. ARNOLD. I would be very glad to have Mr. Maier or Dr. Knutson discuss that, because that does come under their department, and they are working on that development.

The CHAIRMAN. Mr. Kleinfeld, call the next witness.

Mr. KLEINFELD. Dr. Forsyth.

The CHAIRMAN. Dr. Forsyth is recalled.

TESTIMONY OF BRUCE D. FORSYTH, D. D. S.—Recalled

Mr. KLEINFELD. First of all; I want to thank you for submitting a lot of additional data to this committee. We appreciate it.

Do you want to read your letter to the committee?

Dr. FORSYTH. First, Mr. Chairman and Mr. Kleinfeld, I would like to tell the committee that I appreciate the time given to us. I realize that time is most essential to you. We had hoped to come up with some technical experts today to let them give information to you which we feel would be of value to this particular committee.

I think it might save time if at this time we could have sworn in some of the technical experts that are with me so that if you want to stop and ask them questions as we go along, after I have read the letter to the committee, we would be very happy to do it. If you prefer to wait, that is entirely up to you.

The CHAIRMAN. You may proceed. We will take care of that.

Dr. FORSYTH. Thank you, sir. I would, at the time we refer to some of these other witnesses, appreciate it if you would let me have the opportunity of telling you some of their qualifications. [Reading:]

I am glad to transmit the attached material in compliance with the request of Mr. Kleinfeld, chief counsel for your committee. This material includes the specific references requested and also supplemental materials which I believe will be helpful to your committee in its deliberations on the subject of water fluoridation.

The material includes a selected list of references and bibliography on the effects of fluorine on health. The first six of these references are concerned with the chemistry of fluorine and its toxicological and physiological effects. These are merely representatives references. Nos. 1 and 3, for example, are textbooks on the subject, whereas No. 5 is a review article covering 117 individual scientific reports relating to the nondental physiological effects of fluorine. Similarly, No. 6, which is a report of a symposium on fluorine and dental health, covers several hundred different references.

Reference No. 7 is a detailed report of the geographic distribution of communities in this country using naturally fluoridated water. As pointed out in my opening statement, this represents a population of more than 3 million people. The next three references, 8, 9, and 10, relate to the amounts of fluorine in foods and to studies on the elimination of fluorine by human subjects who ingested fluorine from various sources in food and water.

The seven references, 11 through 17, are individual reports of the controlled fluoridation projects under way in this country. The first three of these were started in 1945. References 18 and 19 are selected from the numerous reports of Dr. H. Trendley Dean, and his associates of our National Institutes of Health, which pertain to the characteristics and distribution of mottled enamel in this country. These studies established the minimal threshold of this dental condition in relation to the fluorine concentration of the water supply. References 20 and 21 are examples of reports of the physiological effects of waterborne fluorine on humans. These two reports are merely representative of the

extensive research of Dr. McClure and his associates of our National Institutes of Health conducted during the past 20-year period.

The next three references, 22, 23, and 24, relate to the inhibitory effect of fluorine on dental caries, or tooth decay. The first of these, No. 22, is a report of a symposium on the subject and, in itself, refers to several hundred individual studies. The technical aspects of water fluoridation are described in reference No. 25.

It is my impression that the next three references, 26, 27, and 28, will be of particular interest to your committee. These three reports relate specifically to the false claims that the ingestion of fluorine may increase the incidence of cancer. A copy of reference No. 26 is attached. In view of the negative results reported in references 27 and 28 and in consideration of the cancer rates shown below, there is no justification for asserting that fluoridation presents a public health hazard in this regard.

Cancer morbidity and mortality rates, per 100,000, for cities with varying concentrations of fluorides in the public water supplies

TEXAS

	Mortality	
	1948	1949
Cities having less than 1 part per million of fluorine: Nacogdoches, Tyler, Abilene, and Stephensville (total population, 105,334)	88.3	94.9
Cities having 3 to 4.5 parts per million of fluorine: Lamesa, Lubbock, Plainview, and Amarillo (total population, 163,382)	86.3	75.9

Dr. MILLER. Mr. Chairman, if I might interrupt you, Doctor, you are taking that from this report which I presume all the committee members have, entitled "Production of Mottled Enamel Halted by a Change in Common Water Supply," which shows the cities and the areas that have an excessive amount of fluorine in their water?

Dr. FORSYTH. No, sir.

Dr. MILLER. Well, it is the same material that you have here.

Dr. FORSYTH. The same cities.

Dr. MILLER. Same material.

Dr. FORSYTH (continuing):

WISCONSIN

	Mortality, 1945–49
Stevens Point (total population, 16,550): 0.02 part per million of fluorine	136.2
Green Bay (total population, 52,443): 2.6 parts per million of fluorine	131.6

COLORADO—CALIFORNIA

	Morbidity
	1939
Denver (total population, 316,124): 1 part per million of fluorine	518.2
	1938
San Francisco (total population, 1,131,111): less than 0.1 part per million of fluorine	525.9

Dr. MILLER. Are you trying to show that fluorine in water has nothing to do with morbidity, or what are you trying to show by these figures? Because if you are, I must say to you that there are other things besides fluorine which have something to do with morbidity.

Dr. FORSYTH. This is with relation to cancer.

Dr. MILLER. There are other things that enter into the picture.

Dr. FORSYTH. The first is mortality, this is morbidity.

Dr. MILLER. Do you cover age? Does not age have something to do with the morbidity in cancer?

Dr. FORSYTH. Yes, sir. [Reading:]

References 29 to 34 together with McClure's reports, references 5 and 44 through 48, relate particularly to the excretion of fluorides by way of the kidneys. The results of these reports clearly indicated that at least up to 5 parts per million of fluorine in the water supply, the kidneys do an excellent job of carrying out their excretory function. The results of these and other studies of this nature do not suggest a reasonable basis for assuming that the daily ingestion of 1.0 part per million of fluorine in drinking water will induce or aggravate kidney diseases. In this connection reference 5 is of particular interest, as are the mortality data on nephritis shown below.

Nephritis mortality rates, per 100,000 for 4 Wisconsin cities with varying concentrations of fluorides in public water supplies

City	Fluoride concentration	Years	Rate
	Parts per million		
Stevens Point	0.02	1945–49	32.0
Sheboygan:			
Prefluoridation	.03	1940–44	41.3
Postfluoridation	1.2	1945–49	21.7
Green Bay	2.5	1945–49	28.7

References 49 through 59 are selected as representative of the results of studies on the effects of fluoride on bone and tooth formation and on other body tissues. In general, these scientific reports clearly indicate that teeth and the bones are the first structures to show the effects of excessive amounts of fluorine. However, these and numerous other similar studies have in no instance revealed that 1.0 parts per million of fluorine in drinking water has a harmful effect on skeletal and dental tissue.

Many of the questions raised during my appearance before your committee were based on the assumption that there may be a difference in the effects of water having natural versus added fluorides. In the field of chemistry there is no such thing as a natural or an "artificial" fluoride ion. All fluoride ions are the same no matter whence they come. The fluoride in drinking water is present in the form of the fluoride ion and is detected by analysis as such, and not as a particular fluoride compound. In addition to this basic fact of chemistry, the last five references, 60 through 64, conclusively demonstrate that the physiological effects of natural and artificially fluoridated water are identical.

A set of reprints of published reports covering the research work on fluorine done by the Public Health Service is also transmitted with this report. In addition, a copy of a letter from Dr. Kenneth F. Maxcy commenting on this work is attached. Dr. Maxcy, professor of epidemiology, the John Hopkins University, served as chairman of the National Research Council's ad hoc committee on fluoridation.

It would be appreciated if this letter and the attached list of references are made a part of the record.

Mr. Chairman, if I can be of any further service to your committee I shall be very pleased to serve you.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Doctor, when you first appeared before this committee a few days ago, you referred to testimony by the Surgeon General of the Health Service, Dr. Scheele, before the Senate Subcom-

mittee on Appropriations on April 24, 1951. At that time you said, and you quoted:

> During the past year our studies progressed to the point where we could announce an unqualified endorsement of the fluoridation of public drinking water supplies as a mass procedure for reducing tooth decay by two-thirds.

When was the decision reached that you could unqualifiedly endorse the fluoridation of public water as a mass procedure?

Dr. FORSYTH. You mean when was this announcement made?

Mr. KLEINFELD. When was the decision reached?

Dr. FORSYTH. I would have to supply that for the record. I could not give you the exact date.

Mr. KLEINFELD. Well, Dr. Scheele said it was during the past year, and he said that on April 24, 1951. Would he have said it in April of 1950?

Dr. FORSYTH. As I say——

Mr. KLEINFELD. Does anybody know?

Dr. FORSYTH. I am not sure of the exact date.

Mr. KLEINFELD. Approximately.

Dr. FORSYTH. I don't think anyone here knows the exact date.

Mr. KLEINFELD. The approximate date.

Dr. FORSYTH. I do not know I can give you the approximate date, but we can supply it for the record for you.

Mr. KLEINFELD. Well, Dr. Scheele also testified before the subcommittee of the Committee on Appropriations, House of Representatives, Eighty-first Congress, on January 26, 1949, on page 132 of those hearings:

Congressman Keefe asked him:

> When will the Public Health Service announce the experimentation on the fluorination of central water supplies and give that information to the waiting public?

Dr. Scheele said this, and I quote:

> That, Mr. Keefe, is something that should be asked of Dr. Dean, because it is his field. He will be here a little later. We, like all scientists, are conservative, and the one thing a scientist always wants to do is to avoid premature claims. Until we are absolutely certain we do not like to make announcements. While we can be enthusiastic about the results so far, the children in the test towns have not gone quite far enough in their lives to give us the assurance we want before we precipitate large-scale programs of addition of fluoride to public water supplies.

This was in January 1949. So at that time, sir, Dr. Scheele felt that although you gentlemen could be enthusiastic, the experiments had not gone quite far enough to give assurance that large-scale programs should be initiated.

What occurred between January 26, 1949, and about June of 1950, which is the date you gave us in your original testimony here, when you reached the decision that you could give an unqualified endorsement? What additional data received during that year or year and a half caused this change of position of the Public Health Service?

Dr. FORSYTH. As I mentioned, Mr. Kleinfeld, each year we go back and reexamine a certain number of children in Grand Rapids. Each of the other studies, I believe, in the United States are doing the same thing.

At that particular time our study had only been running 4 years. I believe the time that we usually go back is in October, isn't it?

Dr. DEAN. Yes.

Dr. FORSYTH. Steptember and October.

Then, after the examinations are made and the data is then analyzed, then depending upon what comes out of the data depends how your opinions change as you go along. So that information was not available from our Grand Rapids study at the particular time Dr. Scheele testified. It was after that, and that is why opinion was changed.

Mr. KLEINFELD. You got additional data from Grand Rapids?

Dr FORSYTH. We do each year.

Mr. KLEINFELD. That caused your change of position?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. What information did you receive from Grand Rapids that caused you to change from a somewhat qualified endorsement to a categorical unqualified endorsement? What specific data, or information, did you get from Grand Rapids?

Dr. FORSYTH. Since I am an administrator and not a research worker, and since Dr. Dean, who is directly in charge of our program, is here, I think that question should be asked of Dr. Dean.

Mr. KLEINFELD. We will take it from any gentleman here.

Dr. DEAN. I have not been sworn.

The CHAIRMAN. Give your name and address.

Dr. DEAN. H. Trendley Dean, National Institutes of Health, Bethesda, Md.

(The oath was administered by the chairman.)

Dr. FORSYTH. Mr. Chairman, before Dr. Dean starts to testify, with your permission, I would briefly like to tell you that Dr. Dean joined the Public Health Service in 1921.

He was first detailed to the National Institutes of Health in 1931. He has published over 50 articles in scientific, dental, medical, and public health and engineering journals.

He has contributed chapters to six different books.

He has been awarded the Gorgas Award of the Association of Military Surgery in 1949; the John M. Goodell Prize, American Water Works Association, in 1950; the Jarvis Medal of the Dental Society of the State of New York in 1951.

Dr. Dean is one of the leading authorities in the world on fluoridation of communal water supplies and the relation of fluorine to water.

Mr. KLEINFELD. I would like to say I do not think there is any question about Dr. Dean being one of the leading authorities in this field.

TESTIMONY OF H. TRENDLEY DEAN, D. D. S., NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD.

Dr. DEAN. I would say, Mr. Kleinfeld, we got the final evidence on 6-year-olds. In early times you had 3 years of exposure, then you had 4, and then the evidence of 5 to 6 years' exposure, and a large sample of four or five hundred 6-year-olds showing quite a marked drop, around 65 percent, 55 percent at that time, and 65 percent now, and then that you did have final evidence of a group that largely calcified their teeth on this fluoride water. Before that there was an overriding of that time interval.

Mr. KLEINFELD. Dr. Dean, when you say "final evidence," is what you are referring to as additional evidence the fact that the reduction in the incidence of dental caries was now 65 percent?

Dr. DEAN. This is 65 percent in the 6-year-olds on 1951 data.

Mr. KLEINFELD. That is the evidence that occurred between these two dates, which caused the Public Health Service to make this unqualified endorsement, is that correct?

Dr. DEAN. Yes. This is the first year that we have a whole crop of certain specific age moving in that calcified teeth on this water.

Mr. KLEINFELD. How long had the Grand Rapids experiment been carried on at that time?

Dr. DEAN. It started fluoridation on January 25, 1945.

Mr. KLEINFELD. Did you receive any similar data from any of the other cities at which similar experiments were being conducted?

Dr. DEAN. I think from a scientific standpoint, Mr. Kleinfeld, that is the soundest evidence that we have: That here are four or five wholly independent studies—Newburgh, N. Y.; Brantford, Ontario; Sheboygan, Wis.; Grand Rapids; Marshall, Tex. No one person connected with one of those studies has any connection with the other studies—everyone coming out alike.

Mr. KLEINFELD. What I mean is, did you get similar statistics from the others? What did Newburgh show?

Dr. DEAN. They are running along a comparable figure.

Mr. KLEINFELD. Sixty-five percent?

Dr. DEAN. I wouldn't say around 65.

Dr. ARNOLD. Fifty-five to sixty-five?

Mr. KLEINFELD. Fifty-five to sixty-five?

Dr. ARNOLD. That is right.

Mr. KLEINFELD. In what age groups?

Dr. DEAN. Six-year-olds. With each successive passage of time over 1-year interval, then the next age group showed a drop down.

Mr. KLEINFELD. How about the other cities—did they give you similar statistics?

Dr. DEAN. Going along quite comparable.

Mr. KLEINFELD. Have reports been showing a 65 percent reduction?

Dr. DEAN. I would have to look up the reports to make a specific statement as to that number.

Mr. KLEINFELD. For example, Dr. Blayney, who testified here, is conducting the Evanston experiment.

Dr. DEAN. Right.

Mr. KLEINFELD. He testified they are getting much less than 65 percent reduction.

Dr. DEAN. Yes, but he did not start until 2 years after we did. When his study has two more years added to it he should have about the same results we do.

Mr. KLEINFELD. So that this change in position in about a year, or a year and a half, was caused by what you believe to be proof that the reduction in the incidence of dental caries is now 65 rather than 45 or 40 percent; is that correct?

Dr. DEAN. Yes.

Mr. KLEINFELD. When these experiments were begun and carried on, was it determined that children of various ages, as well as adults of various ages, should be medically examined periodically to de-

termine whether or not possible harmful or deleterious effects were occurring?

Dr. DEAN. New York State conducted a number of medical examinations, but in our field studies we worked in fluoride areas in studying people. We did not see any particular need in studying Grand Rapids when you had three or four million people already using fluoride waters.

Mr. KLEINFELD. Well, answer my question directly, sir. These experiments were set up to watch the reduction, if any, of incidence of dental caries and that is all?

Dr. DEAN. We ran urinary studies, bacteriological studies, and studies of that nature.

Mr. KLEINFELD. I want to get this straight. I think I am trying to put my question understandably. If not, I will rephase it.

Dr. FORSYTH. Maybe I can help you there.

Mr. KLEINFELD. Let me finish my question, sir. I will give you all the time you want.

When these experiments were set up, let's say Grand Rapids or Evanston or Newburgh, N. Y., was it explained specifically at the time these projects were set up that apart from watching the reduction of the incidence of dental caries, regular periodic medical examinations on children and other groups of the population would be made?

Dr. DEAN. Newburgh, N. Y., did.

Mr. KLEINFELD. Now the report that I have examined from Newburgh indicates they make only pediatric examinations on children. Is that incorrect?

Dr. DEAN. I thought they were also studying older people. I know they are making complete pediatric examinations, for example.

Mr. KLEINFELD. I say the report which I have only refers to pediatric examinations.

Dr. DEAN. I would have to look it up.

Mr. KLEINFELD. So again I say, this change in position which caused you to endorse unqualifiedly the mass fluoridation program in those cities which do not have the requisite amount of natural fluorine in their water, that change was caused by the opinion gotten primarily from the Grand Rapids study that there was a reduction up to 65 percent in the incidence of dental decay. Is that right?

Dr. DEAN. It is a point around there. I don't say specifically 65, but maybe 55; but it was a marked reduction in dental caries.

Mr. KLEINFELD. Then, as I understand you, your decision to endorse unqualifiedly this program was not based on any new specific experimental work connected with medical aspects of the program?

Dr. DEAN. No; we had done that before.

Mr. KLEINFELD. Where did you do that before?

Dr. DEAN. A study down at Bartlett and Cameron, Tex., on very high fluoride concentrations. We did that about 1943.

Mr. KLEINFELD. But you did not conduct any such experimental work in any cities whose water was being artificially fluoridated?

Dr. DEAN. No; we haven't, except to take urine samples, because we felt we had done that work before.

Mr. KLEINFELD. In areas which have naturally fluoridated water?

Dr. DEAN. Yes.

Mr. KLEINFELD. Tell me, Doctor, as I understand your testimony, you are not willing to depend on the statistics from these naturally

fluoridated water areas for your figures on the reduction in the incidence of dental caries; is that right?

Dr. DEAN. That is what we postulated this whole Grand Rapids study on—the fact that you did see this reduction in a natural fluoride area.

Mr. KLEINFELD. But you wanted to find out in an artificial fluoridation program just what the reduction incidence would be; is that correct?

Dr. DEAN. What it ended up, Mr. Kleinfeld. In the 21 cities, we saw this difference of three to one between fluoride and fluoride-free populations. We set up a hypothesis, a dental caries fluorine hypothesis, and obviously the next step in scientific procedure would be to subject this hypothesis to experimental verification by adding fluoride to a fluoride-free water, and it is purely experimental verification of the hypothesis.

Mr. KLEINFELD. I see. You wanted to get experimental verification of one or two things. Did you want to get experimental verification of the reduction of incidence in dental caries, or did you want to get experimental verification of the fact that as far as you knew from your hypothesis no adverse physiological or medical consequences had ensued?

Dr. DEAN. No; we were interested in observing whether or not we would get a reduction in dental caries, because we can see no difference between a fluoride ion in a natural water supply and one that is added.

Mr. KLEINFELD. Dr. Forsyth, in your letter which you read to the committee, you refer on page 1 to three references—8, 9, and 10—which relate to the amount of fluorine in foods and to studies on the elimination of fluorine by human subjects who ingested various quantities of fluorine from food and water sources. Will you please explain to the committee just what those reports demonstrated?

Dr. FORSYTH. Mr. Chairman, I do not have those references with me, sir——

Mr. KLEINFELD. I will give them to you.

Dr. FORSYTH. Just a minute, Mr. Kleinfeld, please. We had asked Dr. McClure, who has done considerable research, as you know, since 1931 on fluorine. He is a graduate student from the University of Illinois, where he received his Ph. D. under Dr. Mitchell in 1936. He joined our staff of the National Institutes of Health and continued research on fluorine and dental health problems ever since then.

Now Dr. McClure, as you know, is sick today and could not be here, but Dr. Zipkin, who is one of his associates at the National Institute of Dental Research, is in the room, and I would very much like to ask him to be sworn at this time and answer your questions in connection with this reference. He is the technical expert in this field. I am not qualified to answer your question in reference to this particular statement.

Mr. KLEINFELD. Did you want this other gentleman to answer this question?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. Mr. Chairman, we might do so.

The CHAIRMAN. All right.

Dr. FORSYTH. I might give his qualifications.

Mr. KLEINFELD. We know his qualifications.

The CHAIRMAN. Give the reporter your name and address.

Dr. ZIPKIN. Dr. Isadore Zipkin, National Institutes of Health, Bethesda, Md.

(The oath was administered by the Chairman.)

The CHAIRMAN. Answer the question.

TESTIMONY OF ISADORE ZIPKIN, PH. D., NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD.

Mr. KLEINFELD. First, are you a medical doctor?

Dr. ZIPKIN. No; I am not. I am a Ph. D. in biochemistry.

Mr. KLEINFELD. Did you hear the question I asked Dr. Forsyth?

Dr. ZIPKIN. Yes, sir.

Mr. KLEINFELD. Please answer it.

Dr. ZIPKIN. I have a statement here from Dr. McClure in which the answer to your question, I believe, is incorporated.

The CHAIRMAN. Are you able to answer the question?

Dr. ZIPKIN. Would you please restate that question?

Mr. KLEINFELD. Dr. Forsyth, in his letter to the committee which he just read, referred to three references—8, 9, and 10— which relate to the amount of fluorine in food and to studies on the elimination of fluorine by human subjects who ingested various quantities of fluorine from food and water sources.

I asked him to explain just what those references were intended to demonstrate.

Dr. ZIPKIN. The work done at Illinois with the conscientious objectors who received fluorides indicates——

Mr. KLEINFELD. I am sorry, Doctor. Do you know the three references to which I am referring?

Dr. ZIPKIN. I don't have them at hand.

Mr. KLEINFELD. Let me read them to you. No. 8 is: "McClure, F. J.: Fluorine in Foods, Public Health Report 64: 1061, August 26, 1949."

Dr. ZIPKIN. I am aware of it.

Mr. KLEINFELD. No. 9 is: "McClure, F. J., et al. Balances of Fluorine Ingested From Various Sources in Food and Water by Five Young Men. Journal Industrial Hygiene in Toxicology, 27: 159, June, 1945."

Dr. ZIPKIN. Yes.

Mr. KLEINFELD. The third one, No. 10, is: "Machle, W. and Largent, E. J. Absorption and Excretion of Fluorides. Part II: The Metabolism of High Levels of Intake. Journal Industrial Hygiene and Toxicology, 25: 112, 1943."

Dr. ZIPKIN. I believe I know those references.

Mr. KLEINFELD. All right, what are they supposed to demonstrate?

Dr. ZIPKIN. The reference in foods, I believe, is more a compilation—I believe Dr. Miller has that reference there—compilation of the fluoride content of the foods. Is that correct?

I believe he indicates there that the normal diets as consumed by the greatest majority of people contain in the order of three-tenths or two-tenths milligrams of fluoride. If we assume or, as has been stated by Dr. McClure, that individuals will consume roughly about a liter of water or 1,200 cubic centimeters, perhaps, they will get about 1 milligram of fluoride. So that the fluoride contributed by the food represents only a portion, perhaps a fifth or a sixth, of the amount of

fluoride that would be consumed in water containing a part per million.

As for his study at Illinois, he states in his conclusions and throughout the paper, I believe, that approximately 90 percent of the fluoride ingested by these five subjects was excreted in the urine.

Mr. KLEINFELD. Five subjects?

Dr. ZIPKIN. Five subjects, I believe.

Mr. KLEINFELD. Young men?

Dr. ZIPKIN. Young men.

Mr. KLEINFELD. Can you draw any conclusions from such a study?

Mr. ZIPKIN. The conclusions in the study point to the fact that in the neighborhood of up to 4 parts per million, about 90 percent of the fluoride is excreted, thus representing a small retention of under 10 percent.

Mr. KLEINFELD. Would you say that such figures are statistically valid?

Dr. ZIPKIN. On a basis of those subjects, they are valid.

Mr. KLEINFELD. On five young men. Would they be valid with respect to five old men?

Dr. ZIPKIN. Well, that study, of course, has not been done, and it is not scientifically proper, perhaps, to transpose information taken at one level to information taken at another level.

Mr. KLEINFELD. What about No. 10, the report by Machle and Largent—did that involve chronic or acute studies?

Dr. ZIPKIN. I believe those are acute studies.

Mr. KLEINFELD. Of course, what we are discussing here, Doctor, is primarily chronic studies, so there is no particular point in spending more time on those references. I do not think anybody is contending that anybody is going to drop dead from this stuff. We are trying to find out if you have information on chronic studies. I do not think these references, 8, 9, and 10, are particularly pertinent.

Dr. MILLER. Doctor, did I understand you to say that you thought the five studies were sufficient to form an opinion that would be conclusive?

Dr. ZIPKIN. I think the investigation of Dr. McClure is a very accurately controlled study, and I believe one of the best studies in that field, and we believe the conclusions from the data obtained there are valid.

Dr. MILLER. Doctor, as a sworn witness here and as a scientist, who, I presume, carries on studies of this type, do you recommend that findings on just five completed studies is enough and should be accepted by scientists and by the public? Are you saying that to this committee, that you are going to accept the studies of five as being conclusive and final, and that recommendations can be made on the basis of what you found in five individuals?

Dr. ZIPKIN. What we can say, I think, on the basis of this study, is that in this study here for these young people, the data indicates. As you perhaps realize, no data is entirely conclusive, and no data can be transposed from one situation to another situation. We do a particular type of experiment. And we believe that in this case on these five young men. We believe the data as we find it because we feel the experiment is adequately controlled.

As far as transposing this data to all young men, we say that we believe it indicates in people of this age group that we do have upwards of 90 percent excretion of intake of 4 to 5 parts per million.

Now if that study is contested, if people do not believe it, they will have to take 20 individuals or 25 individuals. But our data indicates that this is probably a valid conclusion on the basis of the evidence that we have.

Dr. MILLER. On the basis of the evidence that you have, you think you have carried it to a point where it is sufficient evidence to report to the scientific world that here are five cases; this is what we found; so this is the answer?

Dr. ZIPKIN. This is what our data indicates. I do not think in any scientific conclusion you can make the categorical statement, "This is universal dogma." I think our data points to the fact that this is probably a valid conclusion.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Forsyth, I would like to go to references 18 and 19 on page 1 of your letter. You say they are selected from the numerous reports of Dr. H. Trendley Dean and his associates of the National Institutes of Health which pertain to the characteristics and distribution of mottled enamel in this country.

I think we ought to discuss that just a little bit. There are various classifications of mottled enamel, are there not?

Dr. FORSYTH. Yes.

Mr. KLEINFELD. For example, in a book I have here entitled "Fluorine and Dental Health," a publication of the American Association for the Advancement of Science, No. 19, publication committee, H. Trendley Dean and Paul C. Kitchin, page 26 is part of an article written by Dr. Dean.

Are you familiar with the definitions that appear on page 26 of that publication?

Let me read them to you.

"Very mild" is defined as—

small, opaque, paper white areas scattered irregularly over the tooth but not involving as much as approximately 25 percent of the tooth surface. Frequently included in this classification are teeth showing no more than about 1–2 millimeters of white opacity at the tip of the summit cusps of the bicuspids or second molars.

"Mild" is defined as—

the white opaque areas in the enamel of the teeth are more extensive but do not involve as much as 50 percent of the tooth.

"Moderate" is defined as—

all enamel surfaces of the teeth are affected, and surfaces subject to attrition show marked wear. Brown stain is frequently a disfiguring feature.

"Severe" is defined as—

includes teeth formerly classified as "moderately severe" and "severe." All enamel surfaces are affected and hypoplasia is so marked that the general form of the tooth may be affected. The major diagnostic sign of this classification is the discrete or confluent pitting. Brown stains are widespread and teeth often present a corroded-like appearance.

Are you familiar with those definitions, Dr. Forsyth?

Dr. FORSYTH. Yes, I am.

Mr. KLEINFELD. I have here a publication, reprint No. 1678 from Public Health Reports: Mottled Enamel in Texas, United States Government Printing Office, which contains on page 2 pictures of teeth in these classifications. I would like to show you this and ask you whether that is accurate as far as you know. [Handing document.]

Dr. FORSYTH. Again, sir, I would like to refer this question to Dr. Dean, who has done extensive work in this field and who also has a classification of mottled enamel, as you know.

I would like to ask him that question.

Mr. KLEINFELD. Fine.

Dr. DEAN. These, of course, are not actual cases, as you know. This was developed.

The CHAIRMAN. What was that, Doctor?

Dr. DEAN. These are not actual cases, Mr. Chairman. These pictures were developed. The first couple of years we started the study these pictures were developed, and they are artist's conception. We tried to get the pictures here and there and get the artist to paint them in colors so we could show people for an exhibit. But as time rolled on, and we had ample materials to classify, then we started using pictures of actual cases like in that article there [indicating]. But this is purely a medical artist's concept.

Mr. KLEINFELD. At the time that book was published, did you believe those pictures to be accurate?

Dr. DEAN. That is a close approximation of the wide range from a part and a half per million up to 14 parts per million.

Mr. KLEINFELD. Have you changed your opinion on that since then?

Dr. DEAN. Well, I have changed this much: I have gone from these paintings to actual photographs of cases in endemic areas, which you see in that article there. I think the natural picture is much more effective than an artist's concept of it.

Mr. KLEINFELD. I am trying to get it straight, Doctor. Is that or is that not an accurate representation of the actual situation as far as mottled teeth are concerned?

We read your classification, Dr. Dean, you see, and then this publication, too, was offered in part, at least, by you, sir, and this publication contains these pictures. What I am trying to find out is whether these pictures are accurate representations or not.

Dr. DEAN. Those pictures were designed to try to depict the various grades of fluorosis when we did not have the experience and the actual pictures as of that time. I did that in the 1934 survey in west Texas.

Mr. KLEINFELD. And you believe at this time that they do or do not represent——

Dr. DEAN. I would not use an artist's concept of anything if I could get a true photograph of a pathological condition.

Mr. KLEINFELD. Were not true photographs available at the time this publication was issued?

Dr. DEAN. Not a complete range. We had not gotten into the intermediate.

Mr. KLEINFELD. I thought there were areas where mottling had appeared for 50 or 60 years; for example, Colorado Springs.

Dr. DEAN. That is right, and we surveyed up to that time. I started in 1931 and went on up to 1938 in surveying mottled enamel; Texas was the first big place we did in 1934.

Dr. MILLER. I would like to ask a question. Would you, then, say that the artist's conception here is the proper presentation to the public as to what mottling is or not?

Dr. DEAN. I would say it is somewhat of an exaggerated condition in order to depict these different points.

Dr. MILLER. In other words, you were not at that time honestly presenting to the public what mottled teeth were really like.

Dr. DEAN. Inasmuch as we knew it at that time.

Dr. MILLER. It looks pretty bad. I guess that would scare most any mother if they looked at it.

Dr. DEAN. When you get up to very high amounts, Dr. Miller, they are really shot to pieces. I have some pictures here if you would like to see them.

Dr. MILLER. Oh, Doctor, I wish you Public Health people would get down to facts. I was public health director at one time, you know, and I know how we like to sort of overemphasize certain things to make our point. I was guilty of doing that when I was public health director in Nebraska, and we had some interesting things occur. But since I have gotten away from it I have sort of had a little different philosophy.

It rather shocks me now to know what the public health is trying to get A. L. Miller to do to his people in Nebraska, and thank God the people out there can think for themselves and did not accept all the stuff that someone was trying to push down their necks at that time, including myself, because I thought maybe there was something to it. Because I saw pictures like that, I thought, "My God, it is awful. We've got to do something about that."

Well, I will take that out of the record. But it did frighten even me just a little, and this frightens me just a little when the public health people go so far as to mislead and distort a national condition in order to put over an objective they might have in mind.

It is not your fault. I am not blaming you. But it is a philosophy that grew up in public-health agencies.

That is all.

Mr. KLEINFELD. Dr. Forsyth, it is our understanding that in April or May of this year the city of Washington is going to fluoridate its public drinking water; is that correct?

Dr. FORSYTH. That is my understanding.

Mr. KLEINFELD. How much are they going to add in the way of fluorine?

Dr. FORSYTH. I believe the amount is up to 1 part of fluorine per million parts of water.

Mr. KLEINFELD. How was that figure arrived at?

Dr. FORSYTH. I do not believe I can answer that question.

Mr. KLEINFELD. Is there anybody else who can?

Dr. FORSYTH. Dr. Dean?

Dr. DEAN. That figure was arrived at on the basis of the study of the 21 cities and the earlier mottled enamel studies of what level of fluoride would give a marked protection against development of dental caries and still be low enough as not to develop any objectionable

fluorosis. That is the result of plotting a curve on the 21 cities that hit about 1 part per million.

Mr. KLEINFELD. Is that the amount which is recommended by the Public Health Service to the District of Columbia?

Dr. DEAN. I think that is the amount so far as I know.

Mr. KLEINFELD. It is your opinion that no objectionable fluorosis will result by using that amount; is that right?

Dr. DEAN. None will develop at 1 part per million.

Mr. KLEINFELD. Dr. Forsyth, I have here Reprint No. 1721 from the Public Health Reports by H. Trendley Dean and Elias Elvove of the United States Public Health Service, entitled "Studies on the Minimal Threshold of the Dental Signs of Chronic Endemic Fluorosis (Mottled Enamel)," put out by the United States Government Printing Office in 1936.

I would like to get your opinion on the following paragraph:

> For public-health purposes we have arbitrarily defined the minimal threshold of fluoride concentration in a domestic water supply as the highest concentration of fluoride incapable of producing a definite degree of mottled enamel in as much as 10 percent of the group examined.

Is it true that under that definition, in calculating your fluorosis index, communities having fluoridated water which show less than 10 percent of the persons having any degree of mottled enamel are classified as a negative fluorosis area?

Dr. FORSYTH. I believe that question should be directed to Dr. Dean. He is the author of that article.

Mr. KLEINFELD. Is that true, Dr. Dean?

Dr. DEAN. At that time—we have to go back in time—we were studying mottled enamel, and we were setting up a level past which we did not have to go so far as to cut down the cost of defluoridation.

Mr. KLEINFELD. What was that level?

Dr. DEAN. Approximately 1 part per million.

Mr. KLEINFELD. I mean what percentage of the population?

Dr. DEAN. We were working on, I think, 10 percent is what we said there. Since then, in the light of increased information and increased observation, I have gone away from that percentage and went into a weighted-average index in that article that you read from the Triple AS. The index, I think, covers the picture better.

Mr. KLEINFELD. What conclusions have you come to now? What percentage do you feel should be ignored, if any, in determining whether mottling will be substantial enough to be considered?

Dr. DEAN. I would certainly ignore anything up to 15 percent, when you understand how the 15 percent is calculated. That may be a slightest little white fleck on a cusp of a back tooth. Maybe 2 out of 24, 25 teeth in the child. You can classify that as "very mild" or throw that into "negative." If you want to be ultraconservative and call that slightest fleck fluorosis, you can go on a 15 percent. Nobody sees it or knows it.

Mr. KLEINFELD. Go up to 15 percent; is that right?

Dr. DEAN. Yes. There is no brown stain or dull white opacity of the tooth.

Mr. KLEINFELD. Does the 15 percent include the category of "questionable"?

Dr. DEAN. No.

Mr. KLEINFELD. So that besides the 15 percent you may have another additional percentage of people or children having some degree of fluorosis who are not included in the 15 percent; is that right?

Dr. DEAN. Well, questionable is so very slight you don't know exactly what it is. You got to get a mirror and got to balance your light three or four ways around the tip of the tooth. You don't know what it is.

Mr. KLEINFELD. In your statistics, the classification "questionable" is included with the normal rather than people suffering from fluorosis?

Mr. DEAN. Right; because if you only got one tooth with the slightest fleck on it, you will throw it in the "questionable." And you find that in nonfluoride areas, you know.

Mr. KLEINFELD. Isn't it a fact, Doctor, that any degree of fluorosis of the teeth caused by fluorine or fluoride is an abnormality?

Dr. DEAN. It is possibly a slight change in calcification.

Mr. KLEINFELD. Isn't that an abnormality.

Dr. DEAN. Yes. It is a very good abnormality.

Mr. KLEINFELD. From the viewpoint of reduced dental caries?

Dr. DEAN. Yes.

Mr. KLEINFELD. If the city of Washington goes ahead with its program, from what you say, the committee must understand that approximately 15 percent of the population, without including the "questionable" category, will be suffering from some degree of mottled teeth.

Dr. DEAN. No, sir; not mottled teeth. I would say that very slight flecks, maybe one or two millimeters on a molar or bicuspid tooth. What we talk about mottled enamel, let's get into something aesthetically undesirable and observable to people.

Mr. KLEINFELD. Let me ask you this, Dr. Dean: Are you in a position to tell this committee now that if the fluoridation program of the District of Columbia is put into effect, no children will suffer from mottling of teeth which will be observable?

Mr. ABERNETHY. Why confine it to the District of Columbia? Why not just say any section?

Mr. KLEINFELD. Any section?

Dr. DEAN. On the basis of the epidemiological evidence, yes, they will not have objectionable mottled enamel at 1 part per million.

Mr. KLEINFELD. Will any of these children have mottled teeth which can be noticed?

Dr. DEAN. Not on the basis of our observation of over 7,200 children in the 21 cities over the range of different concentrations. You are not going to see any objectionable mottled enamel at 1 part per million.

Mr. KLEINFELD. Who decides what is objectionable, Doctor?

Dr. DEAN. Well, I would say if it attracts attention, if you develop a brown stain or something of that nature.

Dr. MILLER. What would be an undesirable degree of fluorosis, in your opinion?

Dr. DEAN. In my opinion, anything that attracts attention. If they have a dull white opaque chalky tooth instead of a translucent tooth, that is objectionable. If they pick up any brown stain, that is objectionable. Anything that would be of a noticeable nature.

Mr. KLEINFELD. If a child had white spots on the front or side teeth, would that in your opinion be objectionable?

Dr. DEAN. How large?

Mr. KLEINFELD. Pardon me?

Dr. DEAN. How large?

Mr. KLEINFELD. Small.

Dr. DEAN. The whole tooth or just something the size of the head of a pin?

Mr. KLEINFELD. Let's take all the categories of size—the head of a pin, the whole tooth, the half tooth, a quarter tooth.

Dr. DEAN. Take for instance a very small pinhead type of white opacity. You can go through Washington or any other city now where you have not got fluorine and find defective calcified spots.

Mr. HORAN. I'd like to ask a question there, Mr. Chairman.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. How would you tell whether something undesirable in the teeth was caused by fluorine or by some other substance present in the water?

Dr. DEAN. I think fluorine is the only thing that causes a change—fluorine in the water is the only water-borne condition that will cause it. But now there are a lot of other conditions that may simulate fluorine in the advanced stages of hypoplasia.

Mr. HORAN. That is my reason for asking that question. We do know, do we not, from past experience and investigations that the absence of certain minerals in water will produce hairless pigs and lead to a whole community having poor teeth? Iron in the water will do the same thing.

Dr. DEAN. Particularly cistern water supplies will result in very, very defective decayed teeth. And you can have other youth abnormalities, or, say, childhood fevers. If they occur at the time the tooth is calcifying, you will have very marked hypoplasia, defective structure, as bad as this severe mottled enamel we are looking at, and not caused by fluorine at all.

Mr. HORAN. In fact, some communities add iodine to the water, do they not?

Dr. DEAN. They did for a while, but that has been pretty much supplanted by adding iodine to salt.

Mr. KLEINFELD. Then, Doctor, as I understand you, it is the firm, definite, unqualified opinion of the Public Health Service that the fluoridation program of Washington, D. C., and other cities, will result in no children whatever suffering from, let's say, mild or very mild mottling of the front teeth?

Dr. DEAN. I would not expect any from the category of mild on up to severe.

Mr. KLEINFELD. Would you expect any very mild?

Dr. DEAN. Occasionally. Now you understand what I mean by very mild—1 or 2 millimeters, maybe, on the tip of a cusp, particularly on a back tooth.

Mr. KLEINFELD. And you feel that no adverse consequences of that sort will occur to any children no matter what their nutritional status is, no matter what any other variables may be present?

Dr. DEAN. No. I think over the group that you would have that picture as I stated.

Mr. KLEINFELD. You may have some with some spots on their teeth, may you not?

Dr. DEAN. I want to reiterate, small white flecks, particularly on the back teeth and very small.

Mr. KLEINFELD. Well, the very mild category as you have in here is—

small opaque paper white areas scattered irregularly over the tooth but not involving as much as approximately 25 percent of the tooth's surface.

Now would you say that in such a program as is being contemplated here no children would have very mild mottling such as you defined it here?

Dr. DEAN. Well, you have got to break some place—100 percent, 50 percent, 25 percent. Now that 25 percent, you can have one with less, with only 2 or 3 percent of the tooth surface.

Mr. KLEINFELD. Yes.

Dr. DEAN. That is thrown in very mild.

Mr. KLEINFELD. You can get under your definition as much as 25 percent?

Dr. DEAN. Sure, but I got to use that classification, got to use up to 1.7, 1.8—so I have to leave a leeway of 25, 50, 100 percent. Because if you are going through a range from zero up to 6 or 8 parts per million—I used that classification a lot around 1.8, but when getting into 1.9 parts per million, you get around 25 percent of the tooth surface.

Mr. KLEINFELD. I am not sure whether we are talking about questionable or very mild.

Dr. DEAN. You asked me about very mild.

Mr. KLEINFELD. You think that no children in these areas which are now contemplating fluoridating their water supplies would suffer from very mild fluorosis as defined by you in this book?

Dr. DEAN. You can have a few cases of very mild fluorosis; yes.

Mr. KLEINFELD. But you are not going to get up to mild and you are not going to see it on the front teeth?

Dr. DEAN. I think we examined 16,000 teeth at Aurora, Ill., which has 1.2, and there was only 0.4 of 1 percent of those teeth where it showed on the front teeth, and that was very small white flecks.

Mr. KLEINFELD. Well, Dr. Dean, or Dr. Forsyth, I have a booklet here, a pamphlet entitled "Dental Effects of Exposure to Fluoride-Bearing Dakota Sandstone Waters at Various Ages and for Various Lengths of Time," by A. L. Russell, D. D. S., M. P. H., South Dakota State Department of Health, Pierre, S. Dak., reprinted from the Journal of Dental Research, volume 28, No. 6, December 1949. Are you familiar with that?

Dr. DEAN. Yes, sir; I have read it.

Mr. KLEINFELD. Well, here is what the first paragraph of this pamphlet says:

The first report in this series described the examination of 2,140 white elementary- and high-school children of Mitchell, S. Dak., a city of 11,000 people which accidentally fluorinated its water supply for a period of 18 months subsequent to August of 1935. Of 873 children with continuous residence, 339 between the ages of 11 and 15 years had been exposed to a mean level of about 1.15 parts per million of fluorides at some time prior to the eruption of their first permanent molars. No caries-inhibitory effect could be demonstrated in these children at the time of examination, about 10 years after Mitchell reverted to a low-fluoride water, though about 8 percent of them exhibited mild or very mild dental fluorosis.

How would you explain that, Doctor—8 percent exhibited mild fluorosis, which is pretty serious; is it not?

Dr. DEAN. No; I don't think mild is serious, but I wouldn't want it. I don't consider it serious.

Mr. KLIENFELD. You do not think children would want mildly mottled teeth as shown in these pictures, do you?

Dr. DEAN. I wouldn't consider mild in the category of the attention-attracting type of mottled enamel. But we certainly don't want any mild when we are talking about fluoridation. We don't want to go that high and don't have to go that high.

Mr. KLEINFELD. You would not want to recommend a fluoridation program which caused mild or very mild mottling in 8 percent of the children?

Dr. DEAN. I don't want to recommend any fluoridation where you get any mild.

Mr. KLEINFELD. How would you explain this study, Dr. Dean?

Dr. DEAN. Well, of course, first you know in South Dakota you got fluorides all over the eastern part of the State. And some of those waters run up to 3, 4, 5, 6 parts per million. You could have some of these children get a greater fluoride intake than possibly what that analysis shows.

Second, you had a drought out there and you brought in water during that drought.

Mr. KLEINFELD. But the water itself only contained 1.15 parts per million for 18 months.

Dr. DEAN. Yes.

Mr. KLEINFELD. Isn't that significant in your opinion?

Dr. DEAN. We have to know the water history of all of those children from the time they are born until the time their teeth were calcified, because you may have variations in the water there.

Mr. KLEINFELD. Dr. Dean, I have here, "Dental Caries and Fluorine," which I mentioned before, a publication of the American Association for the Advancement of Science. This was 1946. There is an article contained in this book entitled, "Epidemiological Studies in the United States." Are you the author of that, sir?

Dr. DEAN. Yes.

Mr. KLEINFELD. On page 23 of this book a table appears entitled, "Incidence and Distribution of Endemic Dental Fluorosis (Mottled Enamel) in 7,257 Selected White School Children, Aged 12–14 Years, Classified According to the Degree of Affection."

Let's look at some of them.

For example, we have Maywood, Ill., where they had 1.2 parts per million fluorine in the water, and they examined 171 children. Sixty-seven were found to be normal. Forty-seven were found to be questionable. These are included with the children who were free from dental fluorosis. But of these 171 children, 50 were found to have very mild mottling and 7 were found to have mild mottling.

Dr. DEAN. That is right.

Mr. KLEINFELD. Is not that a significant degree of mottling?

Dr. DEAN. No; because you haven't got continuous history at Maywood. If you look at the original report you will find a footnote that about 6 or 8 years before the Maywood wells were about 1.5, and then they plugged a well back.

Mr. KLEINFELD. We will then discuss Aurora, Ill., in the same State, with 1.2 parts per million of fluorine. Six hundred and thirty-three children were examined; 337 found to be normal; 201 were found to be questionable. Those 201 questionable were included with the normal to constitute a number which were considered to be absent from dental fluorosis. Eighty-eight children were found to have very mild, 7 were found to have mild dental fluorosis or mottling. Isn't that a significant fact, sir.

Dr. DEAN. You know that is based on as few as two teeth, not the whole mouth. Any time you got two teeth, throw it in the highest category.

Mr. KLEINFELD. Dr. Dean, these are your figures, are they not?

Dr. DEAN. Yes.

Mr. KLEINFELD. Go ahead. Based on as little as two teeth being affected?

Dr. DEAN. Yes. If you got 24 or 25 teeth in there, if you get two teeth that you can call a mild, you throw the whole care into the highest category just in the interests of understating it rather than overstating it.

Mr. KLEINFELD. Well, these two teeth could be front teeth, too, could they not?

Dr. DEAN. No, they would invariably be the second bicuspid or molar teeth, calcified at a later date.

Mr. KLEINFELD. Would you say it is impossible to have front teeth mottled?

Dr. DEAN. It wouldn't be impossible, I wouldn't say. I would have to recheck the data to see if any cases were front.

Mr. KLEINFELD. In any event, 7 children had mild mottling, 88 children had very mild mottling. Is that correct?

Dr. DEAN. Yes.

Mr. KLEINFELD. Let's look at Joliet, which contained 1.3 parts per million of fluorine. Four hundred and forty-seven children were examined; 181 of the 447 were considered to be normal; 153 were considered to be questionable, again included with the normal to constitute a group which was considered to have no mottling. Now out of the 447 children, 99 were found to have very mild mottling, 14 were found to have mild mottling; is that correct?

Dr. DEAN. Yes.

Mr. KLEINFELD. Let's discuss Kewanee, for example, which contained 0.9 parts per million of fluorine, which is, of course, less than 1.1, 1.3, or 1.5. There were 123 children examined. Sixty-five were were found to be normal; 43 were found to be questionable. Thirteen had very mild mottling; 2 had mild mottling. Is that correct?

Mr. DEAN. If that is what it says, yes.

Mr. KLEINFELD. And in Marion, Ohio, the water contained 0.4 parts per million of fluorine. Two hundred and sixty-three children were examined; 151 were found to be normal; 96 questionable, 14 had very mild mottling; 2 had mild mottling.

Dr. DEAN. Now again, on Marion, if you look up the original report, you will find a description of the water supply that during the first couple of years of the lifetime of those older children they were using water supplies that contained 1.2. Then they put in a fluoride ash treatment plant for softening, and that reduced the soda lime con-

tent down to 0.4. But in the early first couple of years of these children's life it had 1.2 in the supply there.

Mr. KLEINFELD. All these figures were considered significant enough to put in your booklet here.

Dr. DEAN. Yes.

Dr. MILLER. I would like to ask the doctor a question here, Counsel.

Mr. KLEINFELD. Yes.

Dr. MILLER. What is the policy of the United States Public Health Service in relation to those towns—the towns we represent up here—that already have maybe 1.5 parts per million of fluorine or more? What is the policy?

Dr. DEAN. There is a study being conducted in Dr. Knutson's division in an attempt to remove the excessive amounts of fluoride—defluoridation plants. That is in the experimental stage.

Dr. MILLER. How low would you recommend it be removed?

Dr. DEAN. Down to about a part and a half, which is the Public Health Service drinking-water standards.

Dr. MILLER. Do you know how many towns have excessive amounts of fluorides in the water?

Dr. DEAN. I would say around 300. No, about 400.

Dr. MILLER. In discussing Missouri and Nebraska, this map here does not show any fluorides in the water. We have sort of been bragging out there, and I think the record shows that the people of Nebraska and Missouri have better teeth than any place in the United States.

Dr. DEAN. You have some down there in the lower left-hand part of Nebraska. It is not on that map. It is down at Scottsbluff, Nebr.

Dr. MILLER. I missed it.

Dr. DEAN. And starting to pick up some fluorides in Missouri around Centralia.

Dr. MILLER. There is some discussion about whether fluoride is sort of a mass medication or not. You are doing it for all the people, the old people along with the youngsters. Have you made any studies as to what happens with those who have chronic diseases in the older people when they get fluorides in the blood stream?

Dr. FORSYTH. Congressman Miller, may I please answer part of that? May I reiterate a statement I made in my opening statement—and I am sorry you were not here when I did the previous time I appeared in front of the committee.

Dr. MILLER. I read your testimony.

Dr. FORSYTH. This is not mass medication. Fluoride——

Dr. MILLER. Doctor, what is your definition of medicine?

Dr. FORSYTH. My understanding of medication would be treating something.

Dr. MILLER. Treating, not preventing diseases?

Dr. FORSYTH. Treating.

Dr. MILLER. Are you a doctor?

Dr. FORSYTH. Dentist.

Dr. MILLER. Not an M. D.?

Dr. FORSYTH. No, sir.

Dr. MILLER. You don't think that medicine includes treatment and cure and prevention of disease?

Dr. FORSYTH. Definitely.

Dr. MILLER. The prevention of disease?

Dr. FORSYTH. Yes; but the word "medication" implies treating something.

Dr. MILLER. Well, medicine, of course, is prevention——

Dr. FORSYTH. We don't——

Dr. MILLER. Just a minute—prevention of disease. And you start putting fluorine in the water, which is a poison, it is put in there for the prevention of dental caries.

Dr. FORSYTH. Yes, sir.

Dr. MILLER. And it is a part of medicine. Now don't try to sidestep that one, because you are out on a limb when you say you are not putting a medicine, a mass medication of people, in the water when you put in fluorine. We vaccinate people against smallpox or typhoid and diptheria, various things. That is the preventive part of medicine.

Dr. FORSYTH. Correct.

Dr. MILLER. And this is the preventive part of medicine to prevent dental caries.

Dr. FORSYTH. Correct.

Dr. MILLER. So it is a part of medicine which is mass medication through water.

I am trying to find out what happens to old people when they take fluorine into their systems.

Dr. DEAN. I would like to ask Dr. Arnold to discuss the study.

Dr. MILLER. What happened with the old people?

Dr. ARNOLD. I will describe one study we have put on in regard to the effect of fluoride waters, and that was referred to some moments ago, in a study put on at Bartlett and Cameron, Tex.

The water supply in Bartlett, Tex., contains 8 parts per million of fluorine naturally. The water supply at Cameron, Tex., contains about 0.3 of a part per million of fluorine. We went into the Bartlett and Cameron, Tex., area with a team of three physicians, three nurses, and myself as a dentist.

We surveyed the families, took family histories throughout the entire community of Bartlett, and we did every third house in the community of Cameron, since Cameron was a much larger community than Bartlett.

We selected those individuals in Bartlett and in Cameron, who had lived in their respective communities more than 15 years of their lives and who had been using the respective water supplies for the time they were living in these communities.

The study, I should say, included a complete medical history, as complete a physical examination as we could do in, shall I say, the temporary medical office set-up that we used. And we did complete X-rays on those individuals.

We did approximately 3,000 X-rays, if I am not mistaken. I would like to correct that figure for the record if it is wrong.

Those X-rays were taken of all the long bones, the skulls, the chests and the spinal column. Any area, of previous fracture, from the history, was re-X-rayed. Those X-rays were sent to the Scott White Clinic in Temple, Tex. They were read there by the roentgenologist in charge of that department. They were also sent to Dr. Saussman, I think, in Boston.

Dr. DEAN. Peter Bent Brigham.

Dr. ARNOLD. He read those X-rays.

Dr. MILLER. Just on the bones?

Dr. ARNOLD. Just on bones.

Dr. MILLER. Were autopsies made on people that died?

Dr. ARNOLD. No.

Dr. MILLER. No tissue examination of kidney, liver, or spleen?

Dr. ARNOLD. No, sir.

Dr. MILLER. Do you think there might be some damage in the soft tissue, outside of the tissue of bones, in taking fluorine over a period of time? Do you think there would be?

Dr. ARNOLD. No, sir; I do not.

Dr. MILLER. You do not?

Dr. ARNOLD. Not from what we found.

Dr. MILLER. One of the men in Texas says his experiments with mice showed that the cancerous mice which had excessive amount of fluorine had a shorter span of life. Are you familiar with that testimony?

Dr. ARNOLD. No, sir.

Dr. MILLER. Whether it is right to deduce that we humans who consume fluorine, perhaps, would have a shorter span of life—that is in the testimony, which you ought to read, of a scientist working with fluorine from the early thirties and doing many experiments with cancerous mice showing the span of life is shortened by use of fluorine. You have no information on that?

Dr. ARNOLD. Dr. Miller, are you referring to testimony of Dr. Taylor from Texas?

Dr. MILLER. I believe it was.

Dr. ARNOLD. And his reference, I think, had to do with his studies on cancer.

Dr. MILLER. I am not sure which man it was.

Dr. ARNOLD. We have Dr. Andervont from the Cancer Institute here that has visited those studies.

Dr. MILLER. But you have not made any studies as to what it will do to older people outside of examination of the bony structure?

Dr. ARNOLD. No, sir. I didn't get to complete our Bartlett study, Dr. Miller.

We did complete laboratory studies on those people in terms of urinalyses and complete blood analyses. And in all the things we could find in that survey, in terms of physical findings the only evidence we found of any change in that population were the changes we found by X-ray, and, as I stated in my previous testimony, bones would be one place that one might likely look for fluoride effects. In those X-rays there were the changes reported by Dr. Saussman—first, I should say that the changes that were shown were not reported from the Scott White Clinic. They did not think there was any difference between the Cameron X-rays and the Bartlett X-rays. Dr. Saussman pointed out there were changes in the Bartlett X-rays which amounted to some changes in the trabecular structure of the bones.

He felt that 12 percent of those individuals who were over 50 years of age and spent more than 35 years drinking 8 parts per million of water did show a coarser trabecular structure of bone. It was of no general health significance.

Dr. MILLER. But you made no examination of the other tissues, vital organs such as the liver, kidney, spleen, as to the effects of fluorine on soft tissues?

Dr. ARNOLD. No, sir; we have not.

Dr. MILLER. Do you know of anyone making those studies?

Dr. ARNOLD. The study I referred to of Dr. Hodge, who is running some analyses of bones from autopsies in fluoride areas.

Dr. MILLER. Bones?

Dr. ARNOLD. Yes, sir.

Dr. MILLER. Not soft tissue?

Dr. ARNOLD. To the best of my knowledge, Dr. Miller, I do not think that Dr. Hodge at the University of Rochester has done that.

Dr. MILLER. Do you think it would be wise to await the findings of some of those results on those chronically ill, those with high blood pressure, or those with kidney or liver disease before we recommend a mass fluoridation of water? Do you think that is important in the study, or should we just confine it to what happens to the children's teeth before the age of six or the age of 12?

Dr. ARNOLD. No, Dr. Miller, for this reason: I think we have definitely, from the epidemiological standpoint, the data that suggests there are no harmful effects from the use of waters even up to 4 and 5 parts per million. We are dealing, in terms of water fluoridation, at 1 part per million.

Dr. MILLER. I am wondering if we are as careful with human beings as we are with our hogs. Here is an agricultural extension service bulletin, University of Wisconsin. By act of Congress we made some moneys available for fluoride and so forth in agriculture. It says:

> Do not feed to bred sows. Sodium fluoride may not be harmful to sows that have been bred, but we believe it would be best to use the treatment only on nonbred animals. If the pigs are treated just after weaning there should be no need for a second treatment before marketing. One treatment is sufficient.

Of course, I do not know what effect these have upon pregnant women, but they are recommending here, an official publication from the Wisconsin Agricultural Department, not to feed fluorides to bred sows. They are apparently coming to the conclusion there is some damage to hogs, and we have not gone that far to find out whether there is any damage to human beings or not.

Do you think the Public Health Service should interest themselves in that phase of fluorine in water before they say to the public, "Why, sure, go ahead and use fluorine; everybody should do it"? Do you think that is important or not?

Dr. ARNOLD. Dr. Miller, I think it is important, and I think we have done that. I think we have studied this in various areas.

Dr. MILLER. I don't see any studies on it.

Dr. ARNOLD. For example, there have been studies in morbidity statistics that are available from Denver, Colo., where they are using 1 part per million in their water supply, and San Francisco, Calif., where the water supply was practically fluoride-free, and there is no evidence in those studies of any increased incidence of disease.

Dr. MILLER. I appreciate that.

I am going to refer to another statement here. The American Dental Association, I think, are here this morning to make some recommendations.

I notice that the last resolve of this resolution applies to public health:

Resolved, That the American Dental Association recommends the continuation of controlled studies of the benefits derived from the fluoridation of water supplies.

I would suggest they put in there also the damage, or perhaps the effects—add the words "unknown effects" it might have. They talk about benefits. You people are always talking about benefits of the fluoride in water.

I wish, for heaven's sake, you would start telling us something about the dangers, because I think we have had ample evidence before this committee it is not all roses so far as fluorides in water is concerned. And so far as I could find, you have not found out whether fluorine in water would be harmful to pregnant women. The agricultural department apparently has.

Mr. ABERNETHY. May I ask one question? I propounded this question earlier, and Dr. Arnold suggested it be submitted to Dr. Forsyth.

It appears as though the doctors who sounded the alarm before this committee on this subject were Dr. Alfred Taylor, Dr. Robert S. Harris, Dr. Veikko Oscar Hurme, Dr. Hans H. Neumann, and Dr. H. V. Smith.

Now along the line that Dr. Miller has just pursued, what work have these people done in this field?

Dr. ARNOLD. Are you asking me, sir?

Mr. ABERNETHY. Any of you. What work have they done? What do they know about it?

Dr. ARNOLD. I know of no work that any of those men have done in the field of fluorine.

Mr. ABERNETHY. I cannot hear you.

Dr. ARNOLD. I know of no work and am not familiar with any work of any of those individuals you named which they have done in the field of fluorine or fluoridation of water supplies, with the exception of the Smiths. The Smiths, I think, Howard and Margaret Smith, did work back in the early thirties and they were the individuals that did demonstrate that fluorine in the water supply did produce mottled enamel. That was the work which was the basis on which Dr. Dean started his investigations of mottled enamel at that time, and also the work of Dr. Churchill.

Mr. ABERNETHY. Do I understand you to say that these people have not conducted any experiments themselves—have done no experimental work?

Dr. ARNOLD. I know of none.

Mr. ABERNETHY. Except the Smiths?

Dr. ARNOLD. Except the Smiths. With the exception that Dr. Taylor was working in some relationship of fluorine to cancer. I am speaking of work that has been done in the relationship of fluorine to dental health.

Mr. ABERNETHY. All right.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Forsyth, I believe that it is the position of the Public Health Service that the dental effect which results from drinking artificially fluoridated water is identical with the effect observed on those people who are drinking naturally fluoridated water; is that correct?

Dr. DEAN. Right.

Mr. KLEINFELD. If that is correct—and you say it is—then we must say that a certain percentage of the children of this city and of other cities of comparable location and climatic conditions will have mottled teeth, very mild and mild mottling of the teeth; is that correct?

Dr. DEAN. Occasionally a small percent of very mild. It would be rather unusual if we had mild at 1 part per million. But in any large group, as in an epidemiological survey, you are going to have sporadic cases.

Mr. KLEINFELD. Then you may have, in these cities, small sporadic numbers of children who may have very mild, and may have mild, mottling of teeth?

Dr. DEAN. That would be a very occasional case if you ever had a mild.

Mr. KLEINFELD. Dr. Forsyth, in about a year and a half, this committee has had a large number of witnesses who have testified on the general subject of the addition of any chemical to any food, any new substance even if it is not considered to be nearly in the category of toxicity as is fluorine, and almost unanimously they have indicated the grave necessity of certain types of experimental studies on animals.

For example, the committee had before it Dr. Roy C. Newton, vice president in charge of research of Switf & Co., and at page 157 of the first volume of this committee's hearings Dr. Newton testified as to what studies he believed should be carried on with animals before any chemical whatever should be inserted into a food product.

He said, for example, "We ought to have acute toxicity studies and we ought to have subacute toxicity studies."

And he said also, "We ought to have chronic toxicity studies."

Most of the other witnesses said the same thing and indicated they believed these to be of great importance.

Dr. Newton said:

> These chronic toxicity studies should be on rats with adequate control groups for a period of 2 years at levels sufficiently greater than those proposed to be used in foods to accentuate any possible physiological effect. Two years were picked because that is the average life span of the rat and gives us an opportunity to carry it through several generations of tests, and also through the life span of an animal.
>
> The exact nature and number of such levels to be studied would be decided upon after the acute and subacute toxicity studies are complete.
>
> As an example of one of the levels to be studied, any chemical substance which is known to be foreign to natural food materials and which is proposed to be used in amounts up to 0.5 percent probably should be studied at a level 100 times the proposed usage.

He said:

> Experiments should be conducted on dogs or monkeys for a period of at least 6 months, but not necessarily more than 1 year at low, intermediate, and high levels, the latter approaching the highest amount that was tolerated without deleterious effects.

He said also:

> In addition, biochemical studies, urine and blood analyses, physiological data, studies on blood components, reproduction through generations, absorption, fate of the material in the body, et cetera, and pathological observations, growth and microscopic examinations on sacrificed animals from the long-term feeding tests, should be carried out to a degree that would indicate no probable effect on the human organism.

Have studies such as these chronic toxicity studies which I have mentioned been carried on by anybody with respect to the addition of fluorides to drinking water?

Dr. FORSYTH. Mr. Kleinfeld, before I ask one of our men at the National Institute of Dental Research to directly reply to that question, let me point out that the adding of fluoride to drinking water, or the presence of fluorides in drinking water, is not a new chemical.

We told you it has been present in drinking water supplies for years and years. We told you that fluoride ions found naturally in drinking water supplies is the same as when it is returned to the drinking water supply in controlled amounts.

So this is not adding a new, unknown chemical to drinking water supplies.

As Dr. Dean has pointed out to you, in talking about the small percentage of people that might have small flecks on their teeth, from an aesthetic standpoint it is not objectionable and could not even be noticed unless it was by a trained observer. An ordinary dentist, unless trained in a study of fluorosis of teeth, would not be able to find these flecks.

Mr. KLEINFELD. With respect to mild mottling, sir?

Dr. FORSYTH. That is right. I would like to ask Dr. Dean, who is best qualified to answer.

Dr. DEAN. Dr. Zipkin.

Dr. ZIPKIN. We have some studies, I think, which we have recently completed that fall in the line of administration of fluoride over a long period of time to rats.

Mr. KLEINFELD. When were these completed, sir?

Dr. ZIPKIN. These were completed within the past year, and the data is in manuscript now.

The CHAIRMAN. Mr. Horan.

Mr. HORAN. As far as I am concerned, I consider fluorine a very useful chemical. I do not think it is on trial here. It is its use we are talking about. I did ask a question I do not want to leave hanging in thin air, Dr. Forsyth.

Dr. FORSYTH. Yes.

Mr. HORAN. Could you tell me if you have made any studies of those who have to handle it as a commercial chemical, any possible effects on them?

Dr. DEAN. That has been studied in industrial hygiene, Mr. Horan.

Mr. HORAN. It has?

Dr. DEAN. Particularly those people exposed to massive doses, 30, 40, 50 times what we are talking about, and also years of exposure.

There was a very interesting study done in Denmark where cryolite from Greenland was processed, and they found those people who were taking in about 30 milligrams of fluorine a day and over long exposures of 15 or 20 years, were getting a very definite bony change. Their urine was very high in fluorine. Then they hospitalized them for several years and at the end of 5 years could see the fluorine elimination decreasing.

Mr. HORAN. I presume that industry took steps to eliminate those dangers.

Dr. DEAN. Then you bring in——

Mr. HORAN. In the interest of fairness, could I have Dr. Dean enlarge on that, if he cares to, when the transcript goes to him, because I think it should be done.

The CHAIRMAN. I have no objection to that.

(The following information was received later for insertion at this point:)

SUMMARY COMMENTS ON FLUORINE—ITS OCCURRENCE, USE, AND HAZARDS BY I. ZIPKIN AND H. T. DEAN WITH ASSISTANCE OF F. J. MCCLURE

FLUORINE IN NATURE

Fluorine occurs, widely distributed in nature as a component of rocks, particularly those of volcanic origin, in the form of fluorspar (calcium fluoride), cryolite (sodium fluo-aluminate), and as a component of rock phosphates. The most important fluorine-containing mineral is fluorspar the major deposits of which occur in Illinois and Kentucky, in Derbyshire, England, and in south Germany. The complex fluorine mineral cryolite is found chiefly in Greenland. The most extensive sources of fluorine are found in the raw rock phosphates of which there are extensive deposits in Tennessee and Florida.

Fluorine in the combined state constitutes 0.078 percent of the earth's crust and is therefore more abundant than chlorine (0.055 percent). Fluorine occurs in soils through incorporation of various fluorine containing minerals. Fluorine in soils varies widely but is usually within the range of about 80 to 500 parts per million.

FLUORINE IN NATURAL WATERS

Fluorine is found in various concentrations in mineral waters and in considerable concentrations in waters from hot springs and geysers of volcanic origin. In Tennessee, for example, surface streams contain fluorine in the range of traces (less than 0.10 p. p. m.) to a maximum of 0.74 parts per million found in a river water which drains an area where rock phasphate is mined. Seventeen collections of rain waters at Knoxville, Tenn., showed an average content of 0.29 parts per million of fluorine. The majority of fluoride waters in the United States have their origin in deep underground aquifiers, and contain 1.0 part per million to 4.0 parts per million or 5.0 parts per million of fluorine.

FLUORINE IN FOODS AND PLANTS

Fluorine occurs in trace quantities in practically all plant and animal materials. Its occurrence in the human and animal body is confined almost entirely to the bones and teeth. Ordinarily over 95 percent of the fluorine in the body is found in the skeletal tissues. Its occurrence in soft tissues and body fluids is negligible.

Fluorine in most edible foods does not ordinarily exceed 0.10 part per million in the fresh edible foodstuffs. Two exceptions are sea foods which may contain as much as 15.0 to 20.0 parts per million of fluorine, and tea which in the cheap grade may contain upward of 200 to 300 parts per million of fluorine while better teas contain about 60 to 70 parts per million of fluorine. An average cup of good grade tea will contain about 0.1 milligram of fluorine. The average American diet exclusive of drinking water contains about 0.3 milligram of fluorine daily.

FLUORINE AS AN INDUSTRIAL HEALTH HAZARD

There are many uses of fluorine in industrial operations. A survey of these various industrial processes involving the use of fluorine compounds as compiled by Medical Director Paul A. Neal of the National Institutes of Health is as follows: (1) Production of aluminum, (2) welding operations, (3) production of magnesium and magnesium alloys, (4) oil refining, (5) steel production, (6) preparation of synthetic cryolite, (7) preparation of hydrofluoric acid, (8) purification of rock phosphate, (9) manufacture of superphosphates for use as fertilizers, (10) manufacture of glass, (11) in preparation of ceramics, (12) by launderers and dry cleaners, (13) tanners, (14) brewers, and (15) in preparation of refrigerants.

During the war an extensive use of fluorine developed in the preparation of fission materials necessary for the production of atomic weapons. During the war and up to the present time there has been a tremendous expansion in the use

of complex organic fluorine compounds. Many unusual properties are acquired by many organic compounds in which fluorine is substituted or added.

As would be expected from its widespread usage in numerous industrial operations, there are a large variety of contacts and exposures to fluorine and its compounds by industrial workers. The precautions taken by manufacturers to safeguard the workers have been under scrutiny by various industrial hygiene agencies, including the Public Health Service. One such study was made by the Public Health Service, i. e., "Health of Workers Exposed to Sodium Fluoride at Open Hearth Furnaces," Public Health Bulletin No. 299.

Generally speaking, the nature of the injuries or harm arising from industrial exposures to fluorine are as follows (quoting from Medical Director Paul A. Neal); Hydrofluoric acid and hydrofluosilisic acid cause severe burns by direct contact with the skin. Hydrogen fluoride can exist in the air as a mist and may therefore be inhaled by workmen. Fluoride dust particles are apt to occur in the air as well as on equipment and on the hands of workmen. These particles constitute an exposure by ingestion.

Air contamination, for example, in aluminum plants, according to Dr. Neal, may range from 0.00054 milligrams to 0.0035 milligrams fluorine per liter of air. A maximum of 0.0041 milligrams per liter has been found. Air samples from a beryllium factory averaged 0.00154 milligrams fluorine per liter. It has been comparatively easy to estimate the extent of the fluorine exposure in industrial operations by means of a fluorine analysis of the urine. As in the ingestion of fluorine in water and food, inhalation of fluorine via air produces a concomitant rise in the urinary fluorine excretion.

FLUORINE HAZARD IN THE NATURAL CRYOLITE INDUSTRY

One of the most thoroughly investigated industrial fluorine hazards is the fluorine exposure of workers in the mining and processing of cryolite. We are greatly indebted to the late Danish physician, Dr. Kaj Roholm, for his classic studies on human fluorine toxicosis as observed in workers long exposed to high concentrations of fluoride as inhaled in cryolite dust. The observations recorded by Dr. Roholm in his classic monograph, A Clinical Hygienic Study, have been an invaluable guide and reference for much of our thinking on chronic fluorine toxicosis. The dust exposure to fluorine as roughly estimated for most of the cryolite workers studied by Dr. Roholm was excessive. It amounted to upwards of 25 to 30 milligrams of fluorine daily for long periods of time. By comparison, a fluoridated drinking water will provide 1.0 to 1.5 milligram of fluorine daily.

A summary of the medical histories of 68 workers of both sexes employed at the cryolite processing works in Copenhagen, Denmark, is as follows:

Eighty-one percent complained of acute gastric disturbances such as loss of appetite, nausea, and vomiting. These symptoms were transitory and disappeared after a short time in the open air.

Thirty-four percent of the workers complained of intestinal symptoms of constipation or diarrhea, or both alternately. These complaints were of chronic nature in nearly all of the 23 workers comprising this group.

Fifty-two percent of the workers complained of circulatory and respiratory symptoms, of shortness of breath on action, cough, palpitation, and expectoration. These symptoms were attributed to dust in the air regardless of the fluorine content.

About 35 percent of the workers complained of symptoms associated with the bones, joints, and muscles such as feeling of stiffness and localized rheumatic pains.

Symptoms of a nervous character such as headache, giddiness, and sleepiness were vague and intermediate.

In the course of autopsy examination of the skeleton, various pathological changes were observed. These were chiefly an increase in the thickness and density of the bones. There were, however, no signs of bone destruction. Eighty-four percent of the workers examined had bone changes and there appeared to be a relationship between the exposure to dust and degree of bone changes. In more than half of the workers the motility of the spine was limited. Clinical examination revealed no other deformities that could be considered typical.

There were pathological changes in the lungs consisting of emphysema (a swelling or inflation of the lungs) and the appearance of fibrous tissue. Motility of the thorax was also greatly reduced. There were no changes from the usual picture in blood pressure. Blood examinations generally showed that

deviations from the normal were few in the hemoglobin, red and white cell counts, bleeding time, coagulation time and other tests. There was a slight to moderate reduction in red and white counts. The urine, skin, nervous system and endocrine glands were essentially normal with only few variations.

A constant and considerable increase of fluorine was found in the teeth of the cryolite workers.

Although there is reason to regard many of the symptoms here recorded as due to cryolite dust exposure, it is equally true that many of the symptoms observed may not have been connected with an excessive ingestion of fluorine per se.

It was concluded in general by Dr. Roholm that cryolite in the doses encountered by these workers had no definite recognizable injurious effect on the general systemic condition or on any specific organ system except bones, blood, and lungs. The excessive excretion of fluorine in the urine did not cause nephritis to a degree which was detectable by the usual clinical examination. No true anemia developed and the blood changes were of no great importance. The most critical symptoms related to the skeletal system, and these are without question attributable to the excessive fluorine exposure.

THE QUESTION OF CRYOLITE SPRAYS IN FRUIT AND VEGETABLE INDUSTRIES

The use of cryolite as a spray for control of the codling moth in the fruit industry necessitated the fixing of a permissible tolerance level of 0.05 grain of fluorine per pound of edible apples and pears, in the form of a spray residue. When this level of tolerance was fixed by the Food and Drug Administration, it was the opinion of authorities on fluorine toxicology that this was a safe limit and would result in no health hazard. The limits now in force seem quite conservative and even though water fluoridation becomes more widespread, there is no apparent reason why this tolerance level should be lowered. The permissible tolerances of fluorine on sprayed fruits, therefore, seems quite adequate to keep the level of fluorine ingestion from sprayed fruits at a very low level.

The question of the probable hazard to orchard workers applying the spray to fruit trees has been answered only indirectly. Thus the Public Health Service in Bulletin 267 reported the results of a very comprehensve survey of the effect of lead arsenate exposure on orchardists and consumers of sprayed fruits. At the time of this survey, 1938–40, cryolite had not had a very extensive use for a prolonged period and emphasis was thus directed to the hazard from lead and arsenic. However, a large population group was studied and their health status reported. Presumably any characteristic systemic effects resulting from the use of cryolite up to that time would have been diagnosed.

It should be noted that while cryolite was used extensively from 1930–38 as an insecticide, lead arsenate was found to be more effective until a method of inverting cryolite spray was devised in 1936 at the Washington State Agricultural Experiment Station. At the present time, however, there are other sprays much more effective than cryolite for control of the codling moth, and there is very little interest in cryolite as a spray in the fruit industry.

On the other hand cryolite has come into rather extensive use in the growing of vegetables, and is used quite extensively in spraying particularly tomatoes, potatoes, beans, etc. In general any spray residue is very readily removed from vegetables and it is generally believed that there is little or no fluorine hazard connected with the use of cryolite as a spray in the growing of vegetables.

(There was discussion off the record.)

The CHAIRMAN. We will hear the American Dental Association at 3 o'clock.

Mr. Horan has another question.

Mr. HORAN. Now the studies were made on the effect of insecticides on those who applied them to fruits and vegetables in 1940.

Dr. DEAN. Yes.

Mr. HORAN. Any findings there on the effect of fluorine on human tissues or on teeth—could I have permission to have a little statement placed in the record on that?

Dr. FORSYTH. Mr. Chairman——

The CHAIRMAN. Wait a minute. I know of no objection to that.

Mr. HORAN. I am not sure that there are any findings, but if they exist I want them. I asked Dr. Dean about it.

Dr. DEAN. I will look it up.

The CHAIRMAN. Dr. Miller has a question.

Dr. MILLER. I wish someone would provide the answer to what effect the long-continued use of fluorine may have on the span of life, what experiments have been conducted on those with diseases.

No. 2, we are having letters from towns and municipalities—"Shall we put fluorides in our water?"

Is it a fair thing to say that experiments are still being carried on, that they are not completed, that they ought to have that information?

Of course, to me as a member of this committee, now I am a little confused about this thing. It is unthinkable we are recommending something in water and they have not completed the experiments, not knowing what happens to the span of life, to people with diseases and so forth. So I would like to have somebody tell me how I can answer some of these questions.

Dr. FORSYTH. We have a statement by Dr.——

The CHAIRMAN. We will adjourn at this time until 3 o'clock this afternoon. How much time will you want with the Public Health?

Mr. KLEINFELD. Fifteen minutes.

The CHAIRMAN. Could your people be back for about 15 minutes, at 3 o'clock, Dr. Forsyth?

Dr. FORSYTH. Yes, sir.

The CHAIRMAN. And the committee will hear the representative of the American Dental Association this afternoon.

(Whereupon, at 12:15 p. m., the committee recessed to reconvene at 3 p. m., of this same day.)

AFTERNOON SESSION

Present: Representatives Hedrick of West Virginia (presiding), Jones of Missouri, Miller of Nebraska, McDonough of California, and Horan of Washington.

Dr. MILLER. We will come to order and proceed with our hearings interrupted at noon with the quorum call.

Go right ahead, Mr. Kleinfeld.

TESTIMONY OF BRUCE D. FORSYTH, D. D. S.; JOHN W. KNUTSON, D. D. S.; H. TRENDLEY DEAN, D. D. S.; AND FRANCIS A. ARNOLD, D. D. S.—Resumed

Mr. KLEINFELD. Dr. Forsyth, in your letter on page 2, you state:

> It is my impression that the next three references, 26, 27, and 28, will be of particular interest to your committee. These three reports relate specifically to the false claims that the ingestion of fluorine may increase the incidence of cancer. A copy of reference No. 26 is attached—attachment B. In view of the negative results reported in references 27 and 28 and in consideration of the cancer rates shown below, there is no justification for asserting that fluoridation presents a public health hazard in this regard.

What report is it that states the ingestion of fluorine may increase the incidence of cancer?

Dr. FORSYTH. Mr. Kleinfeld, we have with us a man from the National Cancer Institute, Dr. H. B. Andervont, who has not yet been sworn in and I believe would be most capable of talking to the point.

Mr. KLEINFELD. I will be very happy to have him.

Dr. FORSYTH. Dr. H. B. Andervont obtained his Ph. D. degree from Johns Hopkins University in 1926 and has been identified with cancer research since that time. He has worked in cancer at Johns Hopkins as a fellow of Carnegie Institute of Washington and as a member of the staff of Harvard Medical School. He joined the staff of Cancer Institute in 1930 and is now chief of the Laboratory of Biology of the National Cancer Institute.

Dr. MILLER. Raise your right hand and be sworn.

(The oath was administered by the chairman.)

TESTIMONY OF H. B. ANDERVONT, PH. D., CHIEF OF LABORATORY OF BIOLOGY, NATIONAL CANCER INSTITUTE, BETHESDA, MD.

Mr. KLEINFELD. Did you hear my question?

Dr. ANDERVONT. Yes, I heard it, sir.

Mr. KLEINFELD. What report is it that states the ingestion of fluorine may increase the incidence of cancer?

Dr. ANDERVONT. Specifically I am not aware of any such report.

Mr. KLEINFELD. This statement of Dr. Forsyth's mentions that.

Dr. ANDERVONT. I do not know what is attached to that, sir, so I cannot answer it. He refers to an attachment, I believe, does he not?

Mr. KLEINFELD. Yes. The attachment does not refer to any report which claims that the ingestion of fluorine may increase the incidence of cancer.

Since the Public Health Service goes into it, I want to know what report the letter of the Public Health Service, which has been read to this committee this morning, dated February 25, 1952, what report are you gentlemen talking about?

Dr. ANDERVONT. I did not prepare that, so I cannot answer that question.

Dr. FORSYTH. Will you give the references to which it refers, please?

Mr. KLEINFELD. References 26 and 27.

Dr. ANDERVONT. That is the question—what is reference 26?

Mr. KLEINFELD. Let me make my position clear. Do you have a copy of your letter?

Dr. FORSYTH. I gave it to the reporter.

Mr. KLEINFELD. Here is one.

Dr. FORSYTH. You also have a copy of the reference material, I believe.

Mr. KLEINFELD. I may say that the reason I asked the question is that as far as I know there has been no testimony before this committee that fluorine has anything to do with the increasing incidence of cancer. Now if you know of any such reports, we would like to have them.

Dr. ANDERVONT. No; not that I know of. The report has been, I understand, of increases in the time of appearance of cancer, not incidence.

Mr. KLEINFELD. So to that extent the report mentioned in this letter is not in existence, is that correct? There are no reports, are there, which claim that fluorine increases the incidence of cancer?

Dr. ANDERVONT. There is nothing in the scientific literature; no, sir.

Mr. KLEINFELD. There is nothing in this committee's hearings to that effect either.

Have you read Dr. Taylor's testimony before this committee?

Dr. ANDERVONT. No, sir.

Mr. KLEINFELD. I want to read to you from Dr. Taylor's testimony at page 3551 of the transcript of the hearings, which contained Dr. Taylor's testimony:

> The results show no change in the incidence of cancer, but rather indicate a shorter lifespan in the mice receiving the fluoridated water. In other words, if a mouse were destined to die of cancer, this disease developed earlier in the group receiving the treated water, and the same was true for other diseases. It is also noteworthy, that the control and experimental animals appeared to be equal in health and vigor in the predisease state.

And on pages 3572 and 3573 here is what Dr. Taylor said. Mr. Kleinfeld is asking a question:

> Did the results of your experimental work indicate in any way that the addition of a compound like sodium fluoride to drinking water has any effect whatsoever on the incidence of cancer?
>
> Dr. TAYLOR. No, no; our data doesn't indicate that.

Later he said:

> In other words, it would mean a shortening of the life span of the human population if we could carry these results over, which, of course, is something that could not be done.
>
> Mr. KLEINFELD. You cannot carry those results over, can you?
>
> Dr. TAYLOR. No, we cannot carry those results over. It might be more severe and it might be less severe, or it might not carry over at all, you see. There are always those possibilities.

But nevertheless, for some reason, you wish to discuss the possible effect of fluoride in connection with the incidence of cancer. If you do, please go ahead.

Dr. ANDERVONT. I am willing to discuss what little I know of it. I know nothing more, sir, than what you repeated there.

There is nothing in the scientific literature and the only thing I have in writing is a letter from Dr. Taylor to Dr. H. Trendley Dean dated March 2, 1951, in which he says that there was no observed change in tumor incidence, but there was a definite acceleration of tumor development in the experimental group.

Mr. KLEINFELD. That is right.

Dr. ANDERVONT. And that, of course, I would question very seriously from the standpoint of a scientist who is interested in experimental cancer—the acceleration.

Mr. KLEINFELD. Did you ever go down to examine Dr. Taylor's experimental work?

Dr. ANDERVONT. I did.

Mr. KLEINFELD. And what did you conclude?

Dr. ANDERVONT. We came to the conclusion that inasmuch as the food he was feeding to his mice contained 30 to 40 parts per million of fluoride, that the ½ part per million in the drinking water could not conceivably have had much influence on his results.

Mr. KLEINFELD. When did you go down there, sir?

Dr. ANDERVONT. In April 1951.

Mr. KLEINFELD. What was the name of the feed used by him?

Dr. ANDERVONT. Purina dog or laboratory chow. I cannot remember which.

Mr. KLEINFELD. And you concluded that those experiments were not valid because of the nature of the diet?

Dr. ANDERVONT. Yes.

Mr. KLEINFELD. Did you then, or did anyone else connected with your organization, conduct a similar experiment using a different diet?

Dr. ANDERVONT. Not that I know of.

Mr. KLEINFELD. Do you know, Dr. Forsyth?

Dr. FORSYTH. Not that I know of.

Mr. KLEINFELD. Attachment B to Dr. Forsyth's letter seems to say that Dr. Taylor reported an increase in the incidence of cancer. That is incorrect, is it not?

Dr. ANDERVONT. Is this the attachment B?

Mr. FORSYTH. That is attachment B.

Dr. ANDERVONT. No, I wouldn't say so at all. I would say in the first group of 67 mice no increase in the incidence or prevalence of mammary tumors was shown.

Dr. Taylor did claim that there was slight acceleration in the earlier appearance of tumors in a small percent of the mice consuming the fluoride water.

Mr. KLEINFELD. Attachment B is written by a Dr. Edward Taylor, director of dental health, State department of health. Is he a cancer expert?

Dr. ANDERVONT. I don't think he is. I do not know his official capacity. I would not want to suggest it. It is probably there in that letter.

Mr. KLEINFELD. It says, "Director of Dental Health."

Dr. ANDERVONT. That is right.

Mr. KLEINFELD. Apparently he is a dentist.

Dr. ANDERVONT. He is a dentist, yes, sir.

Mr. KLEINFELD. And as far as you know, no similar experiments have been carried on since that time by anybody?

Dr. ANDERVONT. Since that time, no, sir, not to my knowledge.

Dr. MILLER. I would like to ask at this time Mr. Chairman, while counsel is looking for another question, whether the Cancer Research Institute—I believe you are located there—if any experiments are now being carried on as to the effects of sodium fluoride in pregnant women and in people with chronic diseases, that is the older people, when they are given sodium fluoride in water.

Dr. ANDERVONT. To my knowledge no such experiments are being done within the confines of the National Cancer Institute.

Dr. MILLER. Do you know of any place where they are carrying on experiments of that type?

Dr. ANDERVONT. No, sir.

Dr. MILLER. Would you be in position to know whether they were carrying them on or not?

Dr. ANDERVONT. No, sir.

Dr. MILLER. Who would? Since you are advocating the use of fluorides in water, who in your group would be in position to say whether such experiments were being carried on?

Dr. FORSYTH. Dr. Dean.

Dr. MILLER. Can you?

Dr. DEAN. I don't know of any experiments being conducted along that line.

Dr. MILLER. Do you think that would be an essential part of the program if we are going to recommend the use of fluorides in water?

Dr. DEAN. No, Doctor, I don't, because we have got three or four million people that are using that much in the United States. We could go out and test that.

Dr. MILLER. Naturally it is in the water in a good many places.

Dr. DEAN. Yes.

Dr. MILLER. Of course, if you started to use sodium fluoride on a universal basis there would still be a great many people in the country, and those in small towns and those who are already getting a dose or an overdose of fluoride that you would not touch.

Since the Agriculture Department has seen fit to make some studies on sodium fluoride in animals, particularly hogs, and they recommend that fluoride in feed is all right for weaning hogs, and they tell how to mix it thoroughly in feed, and then they recommend that you do not feed it to brood sows, sows that are pigging—and I am not sure why they do not do it. But if they found that there was some detrimental effect in the hog, do you not think it would be rather essential to find out whether it was harmful to women?

Dr. DEAN. I think, Dr. Miller, that is a very high dosage of fluoride, using a shot for deworming, is it not? Possibly Dr. Zipkin could tell us what the dosage is.

Dr. MILLER. Three-fourths percent mixture in dry feed of sodium fluoride. It would be rather high.

Dr. DEAN. 750 parts per million, or roughly about 360 parts per million of pure F.

Dr. MILLER. Even though we do not get into this large amount, do you not think there are other places that sodium fluoride might do harm other than just the long bones?

Dr. Arnold testified this morning they examined the long bones, the skeleton, and so forth. A great deal of this is excreted through the urine. Is it not essential to find out whether some damage might be done in other essential organs of the body?

Dr. DEAN. Of course, there is always need for continuing research, but at a concentration that we are talking about of 1 part per million, I cannot visualize where there would be any ill effects at that concentration. There is nothing ever finished in science. It is just like we have been using cowpox virus for 157 years and are still conducting research on it.

Dr. MILLER. I hope you pin this thing down a little more, Doctor. In fact, I introduced a bill for fluoridation of the District of Columbia water supply, at least for discussion purposes. I was more or less open-minded. I wanted to find out what the experts said about it. We didn't get a chance to find out. The Commissioners jumped the gun, as I call it, I think, at the insistence of the Public Health Service to put in fluoridation.

That is the reason I am interested.

I have been in favor of it all along, but there are so many questions that have been raised as to what might be done, and I am amazed that

the Public Health Service has not followed out what might happen to these uncompleted experiments that are going on; why we don't wait to find out what happens to pregnant women, old people with chronic diseases, things of that type. No experiments have been presented to this committee that show there might not be some injury.

You were not sure in 1949 in the literature I have here—not sure you had gone far enough. In this 6 months' period I guess it was the million dollars that just made you sure it was all right. From then on you have been plugging for fluoridation of water, and the country is excited about it and about ready to jump in clear up to the ears, thinking it is going to be a cure-all.

I wonder whether you have moved a little too fast.

Dr. FORSYTH. Dr. Miller, to set the record straight, the million dollars you are referring to had nothing to do with water fluoridation.

Dr. MILLER. Research.

Dr. FORSYTH. The original million dollars that was specially appropriated by the Congress was for the topical fluoride program.

Dr. MILLER. Dental research. Is not that fluorides?

Dr. FORSYTH. That was not dental research. Research was already completed on that. It was to promote the topical fluoride program nationally.

The amount of money appropriated for the dental research for the Public Health Service has never approached the original ceiling which our Research Act carried in 1948 of $750,000. That ceiling was later removed by the Congress. The amount of money appropriated to the Public Health Service for dental research has never approached even $400,000.

No money has ever been carried in our appropriation up to now for promotion of fluoridation of communal water supplies.

Mr. HORAN. By topical research you mean direct application?

Dr. FORSYTH. I mean promoting topical program nationally.

Mr. HORAN. By topical, what do you mean?

Dr. FORSYTH. Topical application of sodium fluoride means the application of it to children's teeth.

Mr. HORAN. Directly?

Dr. FORSYTH. Directly to the children's teeth, that is right.

Dr. MILLER. In view of that, I want to read the report of the Appropriations Committee and what Dr. Knutson said about it. This is an Appropriations Committee report:

> The committee has determined that field demonstration units should be established to operate in the States under a close cooperative arrangement with State health departments, dental societies, and other organizations. It would be the purpose of these units, roughly one mobile unit for each State; to demonstrate to dentists, dental hygienists, State and local health department personnel, et cetera, the correct technique of making sodium fluoride application to the teeth; to serve as a training mechanism for Public Health personnel; and generally to publicize and promote interest in the procedure. In recommending the appropriation of $1 million additional to implement this program of demonstration, it should be clearly understood that the committee does not view this program on the part of the Public Health Service as a permanent fixture. Rather it is the view of the committee that if the demonstration facilities are properly managed they will thoroughly cover the several States and make the procedure so widely known and available, that the Public Health Service can and should withdraw from active participation of the type herein provided for.

And Dr. Knutson says on page 441 of this Nation-wide topical fluoride demonstration program:

> Congress does not see this as a permanent program. I can assure you that the United States Public Health Service views it as a temporary program, a true demonstration program, a program designed primarily to stimulate the establishment of permanent community programs.

There was a million dollars, I believe.

Dr. FORSYTH. That is correct.

Dr. MILLER. That was my reference to the $1 millon in the committee report.

Dr. FORSYTH. But that has nothing to do with the fluoridation of communal water supplies.

Dr. MILLER. It does concern fluorides on teeth, does it not?

Dr. FORSYTH. That is correct.

Dr. MILLER. Which are closely connected with the fluorides in water. In your opinion, is that right—the fluorides in water are to be used for the same purpose as topical application to the teeth?

Dr. FORSYTH. Yes, to prevent tooth decay, but they have no direct relationship. One is applied topically by a dentist or well-trained hygienist under supervision and the other is introduced into the drinking water supply.

Dr. MILLER. Is there no relation at all as to what the results would be when fluorine is taken in water and fluorine is applied topically.

Dr. FORSYTH. No relation. But both prevent tooth decay.

Dr. MILLER. Then there is a relationship.

Dr. FORSYTH. In that they both will prevent tooth decay.

Dr. MILLER. Why certainly. You sit there and say no relationship between them.

Dr. FORSYTH. I say there is no relationship between the amount of money appropriated for that particular project and the water fluoridation.

Dr. MILLER. Well, there must be a connection between fluorides in water and fluorides on teeth. Go ahead.

Mr. KLEINFELD. Doctor, Dr. Forsyth's letter refers to item 27, an article by Tannenbaum, A., and Silverstone, H., Effect of Low Environmental Temperature, Dinitrophenol or Sodium Fluoride on the Formation of Tumors in Mice. Cancer Research 9: 403, 1949.

Are you familiar with that?

Dr. ANDERVONT. Yes, sir, I have that right in front of me.

Mr. KLEINFELD. What diet was used in those animals?

Dr. ANDERVONT. Do you want me to give the details?

Mr. KLEINFELD. No, tell us what was used.

Dr. ANDERVONT. They used a satisfactory diet for laboratory mice, with the addition of sodium fluoride or dinitrophenol.

Mr. KLEINFELD. Is there a particular name for the diet?

Dr. ANDERVONT. Let's see here. I don't think they give any name. The designation is 340, 347, 348, and 350, the scientific procedure for designating.

Mr. KLEINFELD. Is that Purina Fox Chow Meal?

Dr. ANDERVONT. I think they were fed either Purina Fox Chow or Dog Chow Checkered.

Mr. KLEINFELD. Doctor, what percentage of fluorine is contained in that diet?

Dr. ANDERVONT. Nine one-hundredths percent, I believe, which is 900 parts per million. It is an enormous percentage.

Mr. KLEINFELD. I am sorry I did not make myself clear. Not what was added, but how much fluorine was naturally contained in that diet?

Dr. ANDERVONT. I suppose in the diet they fed here they had just exactly what the scientists at the institute found out—approximately 30 parts to million. No, this was not analyzed, they did not analyze it.

Mr. KLEINFELD. Is it not a fact that the amount of fluorine naturally present in this diet and the diet fed to Dr. Taylor's animals contained about the same amount of fluorine?

Dr. ANDERVONT. You could only assume so, but I am willing to assume so.

Mr. KLEINFELD. How about the strains of mice used in both experimental works?

Dr. ANDERVONT. I believe Dr. Taylor used C3H strain. Chicago used dba strain and I believe another strain. I do not believe they used the C3H strain.

Mr. KLEINFELD. Can you look it up?

Dr. ANDERVONT. Yes. They used dba mice, a strain designated as a Swiss strain, and—no, sir, they did not use C3H in this particular experiment.

Mr. KLEINFELD. Are those species frequently used for cancer research?

Dr. ANDERVONT. Oh, yes.

Mr. KLEINFELD. And they are quite susceptible to cancer?

Dr. ANDERVONT. They are the standard strains used in cancer. They give different incidence in different types of tumors. They are susceptible, all of them.

Mr. KLEINFELD. Dr. Forsyth, I think you mentioned topical applications a few moments ago. As I understand your viewpoint and that of the Public Health Service, you have found that a 40-percent reduction in new caries would be effected by the use of topical applications of sodium fluoride; is that correct?

Dr. FORSYTH. Yes, sir.

Mr. KLEINFELD. And it is a comparatively simple method to employ?

Dr. FORSYTH. It is a little time consuming, but it is a relatively simple method in trained hands.

Mr. KLEINFELD. You said at the Labor-Federal Security appropriation hearings for 1952, on page 615, that—

This program has demonstrated the usefulness of dental hygienists and has increased the demand for their services.

Can dental hygienists apply this surface topical application?

Mr. FORSYTH. Yes; under supervision. It depends upon the State law. Some State laws say that a dental hygienist must work under direct supervision; other State laws will allow them to do it without direct supervision.

Mr. KLEINFELD. Are they capable of doing it?

Dr. FORSYTH. Yes; after they are instructed how and have been trained.

Mr. KLEINFELD. So that the employment of the topical application method by trained hygienists, if not contrary to State law, would decrease the incidence of dental caries more than 40 percent?

Dr. FORSYTH. By 40 percent, not more than.

Dr. MILLER. Counsel, I want to call attention to the fact that we were going to have the American Dental Association on by 3:30.

Mr. KLEINFELD. I have one last question, sir.

Dr. DEAN. I think this morning you testified that mild mottling did not occur on front teeth or was not noticeable on front teeth.

Dr. DEAN. It would be very rare.

Mr. KLEINFELD. I have this booklet to which I referred this morning, Fluorine and Dental Health, which contains your article and contains pictures as part of your article. I just want to show it to you and ask whether under the category of "mild" the picture which you have in your article shows mottling on the front teeth or not [showing picture].

Dr. DEAN. Yes, sir, that is an extremely high value in the mild range.

Mr. KLEINFELD. But this is labeled "mild," is it not?

Dr. DEAN. Yes.

Mr. KLEINFELD. And there is discernible mottling in the upper front two teeth; is that not right?

Dr. DEAN. Yes.

Mr. KLEINFELD. I have no further questions.

Dr. FORSYTH. Mr. Chairman, in view of the fact that there has been considerable request for information concerning the relationship of metabolism in general and fluorine, I would like for the sake of the record to request that this statement which was prepared by Dr. McClure, and because of illness he was unable to be here, otherwise he would present it directly to you, he is a biochemist with the National Institute of Dental Research—I would like to have that inserted for your information within the record.

Dr. HEDRICK (presiding). If there is no objection, it will be inserted in the record.

Dr. FORSYTH. Thank you.

(The statement referred to is as follows:)

STATEMENT BY F. J. MCCLURE, BIOCHEMIST, NATIONAL INSTITUTE OF DENTAL RESEARCH, REGARDING HIS EXPERIMENTS ON THE METABOLISM OF FLUORINE

At least three particularly important studies relative to fluorine metabolism may be cited briefly. They furnish significant evidence for our belief that fluorine in drinking water at a level of 1.00 parts per million does not constitute a public health hazard.

In an epidemiological survey conducted during 1933–34 we collected approximately 2,000 urine specimens from high school boys, young inductees at Army examining stations, and from some adult populations. Mr. Kinser and I analyzed these specimens for fluorine and found a remarkably close correlation between fluorine in the urine and fluorine in the drinking water. All the assembled data gave us sound evidence that fluorine is over 90 percent excreted in the urine even when the water contains 4.0–5.0 parts per million of fluorine.

In another experiment conducted in cooperation with Dr. H. H. Mitchell at the University of Illinois—five adult young men excreted by way of urine, feces, and sweat upwards of 90 percent of fluorine ingested in drinking water. This applied to Galesburg, Ill., natural fluoride water, and to Urbana, Ill., water, to which sodium fluoride was added. This evidence shows that a natural fluoride water and a water to which sodium fluoride was added were exactly the same. Both these studies convinced us that fluorine does not accumulate in the body—where added to drinking water. It is eliminated particularly in the urinary excretion.

The kidneys excrete fluorine efficiently and without harm—just as they excrete chlorine, phosphate, sodium, or any other chemical elements ingested in our diet and drinking water.

We have studied also the bone fractures in young adult men—about 3000 were interviewed. Some had 4.5–5.0 parts per million fluorine in their drinking water, all their lives. Some had no fluorine in their drinking water. There was no difference in the number of broken bones, and no difference in the height and weight of these boys and men. Some of the best data on height and weight and fewer bone fractures came from Texas where there we find the most fluorine in the drinking water. Fluorine is no health hazard according to this extensive survey of the incidence of bone fractures, as related to fluoride water.

More recently we studied the development of the carpal bones of children's hands in Lubbock and in Amarillo, Tex. (4.0–5.0 parts per million fluorine in drinking water) versus Cumberland mud (no fluorine in drinking water). These data, based on about 1,800 X-rays show us that fluorine in drinking water has not influenced calcification in these sensitive bones of children's hands.

In addition to these studies on huma population groups exposed to fluoride water, our laboratory studies on the experimental rat have failed to reveal injurious effects even from amounts of fluorine 50 times greater than is proposed for fluoridated drinking water. These studies included histological studies of vital organs, liver, spleen, kidney, lungs, etc. We have found no harmful effects on these tissues.

In view of the evidence we have accumulated and in consideration of the extensive studies of other authorities in this field, we do not regard the fluoridation of drinking water as a public health hazard.

Dr. FORSYTH. In view of the committee's interest in securing full information concerning fluoridation of communal water supplies, if it is not out of order, I would like to suggest some names of people whom the committee might be interested in requesting either a comment from or personal appearance in front of this committee.

Dr. MILLER. Why not present those to counsel, Mr. Chairman?

Dr. FORSYTH. I will be happy to.

Dr. HEDRICK. Do it at a later date, Doctor.

Dr. FORSYTH. Thank you.

Mr. KLEINFELD. I might indicate, Mr. Chairman, that we have so far asked to testify here the Public Health Service, which has appeared twice; the American Dental Association, which asked to testify; the Association of State and Territorial Health Officers, who asked to testify, and we gladly acquiesced. We have asked the American Medical Association to testify. We have asked the National Research Council to testify. We have asked the American Public Health Association to testify.

We asked Dr. Maxcy of John Hopkins, who was chairman of the National Research Council ad hoc committee on fluoridation of water supplies, to testify. Unfortunately he wired us that he is ill and cannot appear.

If you have other names, I will be glad to get them later.

Dr. HEDRICK. Call the next witness.

Mr. KLEINFELD. Dr. Doty.

Mr. CONWAY. Mr. Chairman, in the event I may be asked some questions—I am connected with the association in the capacity of assistant secretary of the association's council on legislation—I would be agreeable to be sworn now.

(The oaths were administered by the chairman.)

TESTIMONY OF J. ROY DOTY, PH. D., SECRETARY OF THE AMERICAN DENTAL ASSOCIATION'S COUNCIL ON DENTAL THERAPEUTICS; AND BERNARD J. CONWAY, ASSISTANT SECRETARY OF THE AMERICAN DENTAL ASSOCIATION'S COUNCIL ON LEGISLATION, CHICAGO, ILL.

Mr. KLEINFELD. Give your full name and address to the reporter, please, Mr. Conway.

Mr. CONWAY. Bernard J. Conway, Chicago, Ill.

Mr. KLEINFELD. Dr. Doty, what is your association with the American Dental Association?

Dr. DOTY. I am employed in the capacity of secretary to the Council on Dental Therapeutics.

Mr. KLEINFELD. What degrees do you hold, sir?

Dr. DOTY. Bachelor of science degree from Monmouth College; Ph. D. degree from University of Illinois.

Mr. KLEINFELD. What has been your professional background since you obtained your academic degrees?

Dr. DOTY. In 1928–30 I taught inorganic and analytical chemistry at Monmouth College, Monmouth, Ill. Subsequent to obtaining my doctor's degree, I spent 1933–35 doing post-doctorate research on the effect of spray residues on plant products at the University of Illinois. And in the period of 1935 to 1943 I was first instructor and subsequently assistant professor of physiology at Louisiana State University School of Medicine at New Orleans.

In 1943 I was employed by the Dental Association, which led to my present position.

Mr. KLEINFELD. Please read your statement.

Dr. DOTY. I am here today to explain the considerations which led the American Dental Association to endorse the controlled fluoridation of fluoride deficient municipal water supplies. With me is Mr. Bernard J. Conway, assistant secretary of the association's council on legislation. Each of us will welcome any questions that bear upon his particular field.

The house of delegates of the American Dental Association, its policy-making body, adopted a resolution endorsing fluoridation of municipal water supplies at its 1950 annual session. That resolution declares:

> Whereas, numerous studies have demonstrated a decreased incidence of dental decay associated with the presence of fluoride occurring naturally in drinking water, and
>
> Whereas, there is a rapidly accumulating body of data derived from direct studies of the artificial addition of fluoride to drinking water, and
>
> Whereas, these data provide convincing evidence of the safety of this procedure and of its benefits in terms of reduced incidence of dental caries: therefore be it
>
> *Resolved*, That in the interest of public health, the American Dental Association recommends the fluoridation of municipal water supplies when the fluoridation procedure is approved by the local dental society and utilized in accordance with the standards established by the responsible health authority, and be it further
>
> *Resolved*, That the American Dental Association recommends the continuation of controlled studies of the benefits derived from the fluoridation of water supplies.

The resolution stresses four fundamental points which are essential to a discussion of the association's stand on fluoridation: First,

the resolution is premised upon an evaluation of studies and scientific data pertaining to fluoridation; second, it is founded upon the scientific data evidencing fluoridation's safety to human beings as well as its dental benefits; third, it declares that the fluoridation procedure should be in accordance with the standards established by the responsible health authority; and fourth, it recommends that controlled studies of its benefits continue.

The responsibility for evaluating research in the many areas that affect dentistry and dental health is assigned to a number of the official agencies of the association. The agencies which have given consideration to fluoridation of water supplies at various times are the Council on Dental Health, the Council on Dental Research, and the Council on Dental Therapeutics. Members of these agencies are association members selected because of their special competence in the field of dental research and in the evaluation of research reports. To buttress the efforts of its evaluating agencies the association appoints consultants and advisors when necessary and, in addition, employs full-time staff members, experts in the field of their parent councils.

The scientific data pertaining to fluoridation are an accumulation of studies and reports over a period of more than 40 years. This includes all available data on mottled dental enamel reported before it was known that excessive fluoride in the drinking water cause this peculiar condition. This includes all available data on the beneficial dental effects of appropriate concentrations of fluoride in the drinking water reported since it has been determined that fluorides do affect the structure of teeth. Finally, this includes all available data dealing with the possibility of harm to human beings caused by drinking fluoride-bearing water. More than 7 years ago an agency of the association made a survey of the evidence then available and concluded that the presence of one part per million fluorine in a water supply is desirable, but the agency did not recommend routine use of fluoridation. The association carefully withheld its endorsement of fluoridation until another 6 years of observation and study provided such convincing evidence of its safety and dental benefits that the dental scientists on the evaluating committees believed they could no longer refrain from endorsing the procedure. The association's endorsement of controlled fluoridation occurred only after an intensive evaluation of all such data.

I have mentioned the reports and studies connected with the peculiar condition of mottled dental enamel. Observations of this condition were reported as early as 1909 by Drs. F. S. McKay and G. V. Black, eminent dental scientists. Actually, they observed and studied an experiment that nature was conducting upon human beings. For more than 20 years only dental scientists were actively studying this apparently pathological condition evidently incurred by persons drinking water from certain sources. During that period of time there was little or no reputable medical evidence reported to suggest that other pathological conditions could be traced to what proved to be high levels of fluoride in the water. On the contrary, scientific findings overwhelmingly support the conclusion that fluorides in drinking water at concentrations even several times that necessary to produce dental fluorosis, are not otherwise harmful to human beings.

At approximately the same time that fluoride in water supplies was determined to be the cause of dental fluorosis, dental scientists were

reporting findings that the incidence of dental decay appeared to be significantly lower in persons afflicted with dental fluorosis. After it became known that fluoride was the causative agent, water supplies in a number of areas in the United States were analyzed. Scientists discovered wide variations in the amount of fluorides present in these waters. Where objectionable dental fluorosis occurred, the concentration was ordinarily found to be several parts per million, in some cases up to 15 parts per million.

Dental fluorosis, however, was absent or inconspicuous where the concentration was below 2 parts per million. But the scientists also discovered that at a concentration of 1 part per million, at which ratio fluorosis did not present a problem, dental decay was as significantly retarded as in localities where dental fluorosis appeared. Thus in communities like Aurora and Joliet, Ill., where fluoride is and has been naturally present at optimum concentration over a considerable period of time, persons who drank from those community supplies while their teeth were forming had a markedly lower caries rate than persons who did not have the benefit of fluoride during the formative period of the teeth. Furthermore, objectionable dental fluorosis in Aurora and Joliet is almost unheard of. Today dental scientists safely anticipate a reduction of 60 to 65 percent of the number of cavities ordinarily expected in a given age group, if that group has been drinking fluoridated water during the dental formative years.

The prevalence of dental disease among the population of this country is extensive. Ninety-five percent of our population is or will be affected with one form of dental disorder or another during a lifetime. Dental decay, furthermore, represents a very high percentage of the incidence of dental diseases afflicting mankind. Studies of the dental-caries problem reveal that the Nation's dental personnel cannot in the foreseeable future repair the effects of dental decay at a rate approaching the rate at which new carious lesions develop. The association's primary responsibility is to protect and improve the Nation's dental health. It has, therefore, a professional responsibility to recommend the proper utilization of preventive measures demonstrated to be effective in the control of dental disease. The association would be delinquent in assuming its responsibility if it did not endorse and recommend preventive measures as soon as adequate demonstrations of their safety and practical usefulness are supported by sufficient scientific evidence. In endorsing and recommending the fluoridation procedure, the association's evaluating agencies are of the opinion that every year that the fluoridation procedure is delayed leads unnecessarily to the denial of dental benefits to vast numbers of American children.

The safety of the fluoridation procedure recommended by the American Dental Association, as well as the benefits, is the particular concern of this committee. The procedure recommended calls for the addition of fluorides to water supplies which are naturally deficient in fluoride ion, in order to adjust the concentration of fluoride ion to approximately 1 part per million. Slight adjustments of that ratio may be desirable according to the quantity of water normally imbibed per individual in a particular geographical region; it will probably be lowered slightly in the warm climates and raised slightly in the cold climates; or it may have to be adjusted seasonally in areas

which have long periods of both high and low temperature. These modified ratios may be found to provide maximum dental benefits without causing detectable dental fluorosis. I should further emphasize the fact that fluoride ions picked up by water in traversing subterranean formations are identical with fluoride ions introduced into water distribution systems through the addition of suitable fluoride compounds.

It may be desirable to consider a few of the reports that are of special interest in relation to the safety of fluoridation. As previously stated, dental fluorosis is regarded as the most sensitive physiological response to small amounts of fluoride. An animal experiment was reported which claimed to indicate that fluoride increased the rate of development of experimental mammary tumors. The report of that experiment indicated that small quantities of fluoride contained in the drinking water of one group of the animals caused them to succumb more rapidly to breast cancer than a like group drinking nonfluoridated water. I would like at this point to read an excerpt from a letter to Dr. Robert F. Korns of the New York Department of Health from Dr. Norman Topping, Associate Director of the National Institutes of Health, pertaining to that experiment:

* * * As a further check samples of the food ration, Purina Dog Chow, fed the mice in the Texas study were obtained and analyzed for fluorine content. Repeated analyses showed that this diet contained between 40 and 45 parts per million fluorine. With a hundredfold disparity between food and water fluorine intake, it is obvious that any effects of the water-borne fluoride would be obliterated.

I am entering a copy of the letter for the committee's record.

Attention has also been directed to the skeleton. McClure studied the possible relation of fluoride (F) in drinking water to bone-fracture experience and height and weight of boys and young men. He could find no evidence of skeletal superiority resulting from residence in a nonfluoride area as compared to a fluoride area.[1]

Another important question is the possibility of accumulation of fluoride in the body. It has been estimated that the amount of fluorine ingested daily through drinking water containing 1 part per million fluorine is about 1 milligram.[2]

It has also been shown that the elimination of ingested fluorine by way of perspiration, urine, and feces is practically complete when the fluorine ingested does not exceed 4 to 5 milligrams daily.[3] A survey of the amount of fluorine in urine specimens of high-school boys and young selectees shows that the concentration of fluorine in the urine is almost identical with the concentration in the drinking water up to about 4.5 parts per million.[4] Other excretion and balance studies have been reported by Machle and his associates which are in accord

[1] McClure, F. J. Fluoride Domestic Waters and Systematic Effects. 1. Relation to bone-fracture experience, height, and weight of high-school boys and young selectees of the Armed Forces of the United States. Public Health Reports 59: 1543 (Dec. 1) 1944.

[2] McClure, F. J. Ingestion of Fluoride and Dental Caries. Quantitative relations based on food and water requirements of children 1 to 12 years old. American Journal of Diseases of Children, 66: 362 (October) 1943.

[3] McClure, F. J., Mitchell, H. H., Hamilton, T. S., and Kinser, C. A. Balances of Fluorine Ingested From Various Sources in Food and Water by Five Young Men. Excretion of fluorine through the skin. Journal of Industrial Hygiene and Toxicology, 27: 159, 1945.

[4] McClure, and Kenser, Fluoride Domestic Waters and Systemic Effects. II. Fluorine content of urine in relation to fluorine in drinking water. Public Health Reports, 59: 1575, 1944.

with the studies just described. Urine excretion studies have also been extended to include measurement before and after the addition of sodium fluoride to a public-water supply. The results indicate that at least a very large proportion of the added fluoride is being eliminated as rapidly as it is ingested.[5]

Some surveys of the amount of certain types of kidney disease in fluoride as compared to nonfluoride areas have not produced any evidence of harmful effects upon the kidneys by fluorine at the levels proposed for the fluoridation procedure. Renal injury in animals has been produced only by extreme doses of fluorine. Rats and swine showed kidney changes when their diet contained 200 to 800 parts per million of fluorine.[6]

The surveys and reports cited constitute only a part of the considerable scientific evidence attesting to the safety of the recommended fluoridation procedure. The association maintains that there is more scientific evidence available to substantiate the safety of adding controlled amounts of fluorides to water than there is for the addition of any chemical to a food or food product. At this point let me emphasize that neither the Council on Dental Health nor the Council on Dental Therapeutics has recommended the addition of fluorides to foods.

The American Dental Association's evaluating agencies are not the only groups which have appraised the safety of fluoridation. The Council on Pharmacy and Chemistry and the Council on Foods and Nutrition of the American Medical Association, as well as the Ad Hoc Committee on Fluoridation of Water Supplies of the Division of Medical Sciences, National Research Council, have reported on the harmlessness of the procedure.

These scientific bodies have appraised the evidence appropriate to their findings in a manner similar to that used by the American Dental Association's evaluating agencies. These groups, not allied in any way with the American Dental Association, considered the evidence pertaining to all physiological effects. Medical, as well as dental scientists, then, are convinced of the complete safety of the association's recommended fluoridation procedure.

In recommending to its State and local societies that they seek to accomplish fluoridation of water supplies in their respective areas, the association's evaluating agencies explicitly state that the procedure be in accordance with standards established by the responsible health authority. Obviously, the safety of fluoridation in operation depends upon establishing proper standards and employing expert control for the procedure and installation; that is, for the appropriate amount of fluoride to be added and over the maintenance of the equipment; the latter will require both approved equipment and personnel adequately trained to keep the fluoride introduction at the specified level.

In the more than 200 municipalities that have fluoridated their water supplies, no serious problems have occurred. The process is relatively simple from an engineering and maintenance viewpoint. Both large and small municipalities have been able to fluoridate their water supplies efficiently and economically. Studies designed to improve the mechanics of fluoridation as well as to increase its dental benefits will continue.

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[5] Nondental effects of trace quantities of fluorine. Dental Caries and Fluorine, American Association for the Advancement of Science, 1946, p. 78.

[6] Kick et al., Fouorine in Animal Nutrition. Ohio Agricultural Experiment Station Bulletin, 558, 77 pp.

This brings me to the final point contained in the association's statement of policy. The American Dental Association recommends that controlled studies of fluoridation's benefits continue. The association wishes to assure this committee that a thorough scientific appraisal of all of the reported effects of fluoridation will continue. As in the past any reported effect will receive attention. The association is sincerely convinced that no pothological conditions will result from proper fluoridation. An unobjectionable form of dental fluorosis may appear in a small percentage of children. It is obvious, too, that the interests of medical and related scientific groups in the nondental effects of fluoridation will keep pace with the association's primary interest in the dental effects. In conclusion I would like to recommend in behalf of the American Dental Association that this committee, if it has not already done so, request a statement from, or extend an invitation to, these eminent scientists:

F. S. McKay, Colorado Springs, Colo.
W. D. Armstrong, University of Minnesota.
H. T. Dean, National Institute for Dental Research.
Philip Jay, University of Michigan.
F. A. Arnold, National Institute for Dental Research.
O. K. Sagen, Division of Vital Statistics and Records, Springfield, Ill.
G. J. Cox, University of Pittsburgh.
F. A. Bull, director of dental education, State Board of Health, State Office Building, Madison, Wis.
D. D. Ast, director, Bureau of Dental Health, New York State Department of Health.
Edward R. Schlesinger, director, Bureau of Maternal and Child Health, New York State Department of Health.
Elias Elvove, National Institute of Health.
F. J. McClure, National Institute for Dental Research.
H. C. Hodge, University of Rochester.
Isaac Schour, University of Illinois.
Joseph C. Tam, University of Minnesota.
R. F. Sognnaes, Harvard University.
J. F. Volker, University of Alabama.
E. J. Largent, University of Cincinnati, College of Medicine.
H. B. McCauley, Baltimore City Health Department.
A. L. Russell, United States Public Health Service.
Thomas J. Hill, Western Reserve University.

This is a representative but not complete list of scientists who have reported data obtained in surveys of human population groups or in animal experiments which are pertinent to the subject of water fluoridation. If the committee desires, I shall present a number of statements and reports that the association believes should be part of the record.

In behalf of the American Dental Association may I thank you for the privilege of appearing here today.

(The letter submitted by Mr. Doty is as follows:)

MAY 17, 1951.

DR. ROBERT F. KORNS,
Director, Bureau of Epidemiology and Communicable Disease Control, State of New York Department of Health, Albany 7, N. Y.

DEAR MR. KORNS: In replying to your letter of April 24, I will summarize our information to date on the question of the alleged relationship between fluorine and the time of appearance of mammary tumors in mice.

According to our information some months past, a brief report was made to a closed session of waterworks engineers, city officials, etc., in Texas in which data were presented which seemed to indicate that fluorine in drinking water at a concentration of 1.0 part per million accelerated the appearance of mammary tumors in strain C3H mice when compared with a control group given water containing no fluorine. The C3H strain of mice is highly susceptible to this type of tumor, about 97 percent of the animals being affected within 8 months in our colonies in the National Cancer Institute. The claim was made that the incorporation of 1 part per million (F) in the water made the tumors appear earlier than usual in these mice.

In view of the implications of this claim, Dr. H. T. Dean, Director of the National Institute of Dental Research, and Dr. H. B. Andervont, Chief of the Biology Section of the Cancer Institute, made a visit to the laboratory of the investigator in question and examined the protocols of the experiments. The following facts emerged:

1. The initial study was based on 21 controls and 20 experimental mice at 1 part per million NaF and 13 controls and 13 experimental mice at 10 parts per million of NaF.

2. The variation between control and experimental groups was not of sufficient magnitude, with the sample size used, to meet any statistical test of validity.

3. It has been the experience of competent workers here and elsewhere in the country that these mice vary considerably with respect to the latent period of the tumor. This is based on results of many experiments involving thousands of mice. The early variations in the fluoride experiment easily come within the normally expected range of variability and could not be considered significant.

4. The amount of fluorine used was based on 1.0 part per million NaF and thus the F concentration was actually 0.4 part per million.

As a further check, samples of the food ration (Purina Dog Chow) fed the mice in the Texas study were obtained and analyzed for fluorine content. Repeated analyses showed that this diet contained between 40 and 45 parts per million F. With a hundredfold disparity between food and water fluorine intake, it is obvious that any effects of the water-borne fluoride would be obliterated.

In addition, several people have collected data on the human cancer picture in fluoride and nonfluoride areas and have found no significant differences in individual types or total incidence and mortality or length of survival after diagnosis.

It is unfortunate indeed that this story became so widely circulated before it appeared in print where it would be open to public scrutiny and criticism. It is our understanding that the study will not now be published. This is not because of any pressure on the investigator but because he was not able to confirm his results in a subsequent experiment and is now conducting another experiment. From our point of view this is regrettable, since we cannot publicly refute a claim that has never been made publicly and the psychological damage done is great.

We have, however, received word from Dr. Edward Taylor, director of dental health, Texas State Department of Health, that the department deplores this whole affair and is in process of preparing a bulletin which will refute the hypothesis that fluorine has anything to do with breast cancer. This bulletin may be of further interest to your group when it appears.

Sincerely yours,

NORMAN TOPPING,
Associate Director, National Institutes of Health.

Dr. HEDRICK. You may proceed, Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Doty, with respect to the names of the eminent scientists which you mention on page 7 of your statement, do you know whether all or most of these scientists are members of or associated with the American Dental Association or the American Medical Association or the National Research Council or the Public Health Service or the American Public Health Association?

Dr. DOTY. Do I know whether or not these individuals——

Mr. KLEINFELD. Are members.

Dr. DOTY. Are members. All of them of those particular groups?

Mr. KLEINFELD. Yes.

Dr. DOTY. Dr. McKay will undoubtedly be a member of the American Dental Association.

Dr. Armstrong is a physician. I am not aware as to whether or not he holds membership in the American Medical Association.

Dr. Dean is, of course, a member of the American Dental Association, as well as an employee of the United States Public Health Service.

Dr. Jay is, of course, a member of the American Dental Association.

Dr. Arnold, you know, of course.

Dr. Sagen is not a member of the American Dental Association. He has a doctor of philosophy degree. He is not a doctor of dental surgery or doctor of medicine.

Dr. Cox has a doctor of philosophy degree. He is a type of member of the American Dental Association.

Dr. Bull is a member of the American Dental Association.

Dr. Ast, I am sure, is a member of the American Dental Association.

Dr. Schlesinger is a physician, so he would not be a member of the American Dental Association.

Dr. Elvove, I am not sure of his degree, but I believe that he is neither a dentist nor a physician.

Mr. KLEINFELD. I do not think we need to go further.

I just want to make this point to you, sir: As you may have heard before, we have asked to appear here to testify on the benefits of fluoridation, in addition to the American Dental Association and the Public Health Service, the American Medical Association, the American Public Health Association, the National Research Council, and the Association of State and Territorial Health Officers.

It is our understanding that these organizations such as yours, in view of their endorsement of this program, are fully conversant or fully familiar with the work of most of the gentlemen you mentioned. We are leaving it to these associations to pick any witness or witnesses they choose to represent them.

Dr. Doty, you discuss on the first page of your statement this resolution adopted by the house of delegates of the American Dental Association. Was the resolution submitted to the membership of the American Dental Association?

Mr. CONWAY. May I answer that question?

Mr. KLEINFELD. Certainly.

Mr. CONWAY. The membership of the association does not pass on policy. Responsibility for establishing policy is delegated by vote to the group known as the house of delegates, which is comparable to the House of Representatives or the Senate of the United States Government. It is the legislative body of the American Dental Association elected democratically.

Mr. KLEINFELD. How many members are there on the house of delegates?

Mr. CONWAY. Approximately 380.

Mr. KLEINFELD. What is the membership of your association?

Mr. CONWAY. The association membership at the moment is approximately 70,000, a little less than 70,000. There are about 80,000 practicing dentists in the country.

Mr. KLEINFELD. Was your membership polled in any way to indicate its views on this resolution?

Mr. CONWAY. The membership—there is no referendum conducted by the American Dental Association. The members elect their house of delegates, and they inform the house of delegates as to the policies that it should be in favor of when it meets at the annual session. As I say, it is very comparable to the legislative body of the United States Government. They are elected members of a policy-making body.

Mr. KLEINFELD. Dr. Doty, the resolution adopted by the house of delegates of the American Dental Association, does it constitute an unqualified endorsement of the fluoridation of the public drinking water of the cities of this country?

Dr. DOTY. In my opinion it does.

Mr. KLEINFELD. Then it is the opinion of the American Dental Association that the fluoridation of public drinking water in cities of this country is unqualifiedly safe?

Dr. DOTY. I might qualify that to this extent: That is according to the recommended procedures. In other words, this is not something to be recommended to be done indiscriminately. It is something to be done under the direction of qualified and trained personnel and in accordance with the standards which have been established by the responsible health authority in each locality.

Mr. KLEINFELD. Let's take the city of Washington here. Then this endorsement, or this resolution of the American Dental Association, is an unqualified statement that no person will be injured in any way by the fluoridation of the public drinking water of the city; is that correct?

Dr. DOTY. I believe that is the conviction of these agencies.

Mr. KLEINFELD. And is it the conviction of the American Dental Association that no children in the city of Washington will suffer from dental fluorosis if this program is inaugurated?

Dr. DOTY. I believe it is their conviction that no children will suffer from any objectionable degree of the condition known as dental fluorosis.

Mr. KLEINFELD. Who determines, Doctor, what is objectionable dental fluorosis?

Dr. DOTY. I would say that that is a type of question which could be more adequately answered by dental personnel themselves. But I think that that represents a degree of concurrence of opinion amongst a large number of dentists who have made examinations of a large number of children displaying the very mild conditions which are all classified under dental fluorosis.

Mr. KLEINFELD. Did the American Dental Association make any independent research studies or investigations before adopting this resolution?

Dr. DOTY. As I have indicated, the American Dental Association, as such, appoints evaluating committees. The members of those committees are men who have actively participated in research studies dealing with fluoridation of water supplies.

The American Dental Association, as such, being a professional organization of a particular type which it is, does not actually carry on experimental studies of this sort.

Mr. KLEINFELD. I have here a booklet, to which we referred this morning, entitled "Fluorine and Dental Health, Publication of the American Association for the Advancement of Science, No. 19," pub-

lication committee, H. Trendley Dean and Paul C. Kitchin, 1942, and an article appears herein entitled "The Investigation of Physiological Effects by the Epidemiological Method," by H. Trendley Dean.

On page 27 pictures appear indicating the mottling in the various categories mentioned by the Public Health Service.

This was shown to Dr. Dean this morning—this is part of Dr. Dean's article in the book to which I have referred. And I want to show these pictures to you and ask you to look at the "mild" classification, look at the teeth listed under "mild." [Presenting document, which is reproduced following page 1684.]

Do you see any mottling there?

Dr. DOTY. I should add, again, that I am not a dentist. No; personally I see nothing there which I, as an individual who am not expert in this field, would recognize as mottling.

Mr. KLEINFELD. I would like to show that to the committee, Mr. Chairman.

Dr. DOTY. I was looking under the one——

Mr. KLEINFELD. I am talking about "mild."

Dr. DOTY. Oh, I see. I am sorry; I was looking at the wrong picture. I see certain spots indicated on there which I would myself, I think, regard as such, as spots.

Mr. KLEINFELD. On what teeth do they appear, these spots?

Dr. DOTY. They appear on several of the teeth.

Mr. KLEINFELD. Front teeth?

Dr. DOTY. They seem to be; yes.

Mr. KLEINFELD. Is that what you have been referring to as unobjectionable?

Dr. DOTY. It is my understanding that this is not representative of what is at the present time referred to as mild mottling.

Mr. KLEINFELD. Please answer the question.

Dr. DOTY. I would say that I might find this effect objectionable, although I would definitely find it less objectionable than I would certain types of restorations resulting from dental decay in such teeth.

Mr. KLEINFELD. Let me ask you again. Your statement refers to certain types of dental fluorosis which you do not consider objectionable. Would you consider the type of dental fluorosis under the label "mild" in the picture before you as objectionable or unobjectionable?

Mr. CONWAY. May I ask counsel a question?

Mr. KLEINFELD. Yes.

Mr. CONWAY. Are these actual photographs or artists' conceptions?

Mr. KLEINFELD. Dr. Dean is here. We will ask him. Are these actual photographs?

Dr. DEAN. Actual photographs.

Mr. KLEINFELD. Now will you answer the question, Dr. Doty? If you cannot, we will go on from there.

Dr. DOTY. As I have said, I am not a dentist.

Mr. KLEINFELD. You represent the American Dental Association, do you not?

Dr. DOTY. I represent the American Dental Association in an administrative capacity.

Mr. KLEINFELD. All right. Please return the pictures.

You referred, Mr. Doty, in your statement, to the cities of Aurora and Joliet, Ill. Now in the book I have here, Dental Caries and Fluo-

rine, a publication of the American Association for the Advancement of Science, to which I referred this morning, on page 23 there is a table, table 11, entitled "Incidence and Distribution of Endemic Dental Fluorosis (Mottled Enamel) in 7,257 Selected White School Children, Aged 12–14 Years, Classified According to the Degree of Affection."

And here for the city of Aurora, with 1.2 parts per million of fluorine in the water, 633 children were examined. 337 were found to be normal, or free from any dental fluorosis; 201 were found to be in a questionable category, which were included with the 337 normal, so that both groups were said to be free from dental fluorosis; 88 children were found to have very mild dental fluorosis; 7 were found to have mild dental fluorosis.

In the city of Joliet, with 1.3 parts per million of fluorine in the water, 447 children were examined; 181 were found to be normal, free from mottling; 153 were found to be questionable. These were included with the 181 normal to constitute a total category of children in whom fluorosis was not present. 99 children were found to have very mild mottling, 14 children were found to have mild mottling.

Now, this mild mottling which 14 children in Joliet had and 7 children in Aurora had, that mottling might have been similar to the mild mottling set forth in the picture we showed you; is that not correct?

Dr. DOTY. Here again I should stress one point—that I am representing here and relaying to you opinions of evaluating groups of the American Dental Association and not acting as an expert in this particular field.

Mr. KLEINFELD. Mr. Chairman, if we can, I suggest that these pictures, appearing on page 27 of an article entitled "The Investigation of Physiological Effects by the Epidemiological Method," by H. Trendley Dean, contained in the booklet entitled "Fluorine and Dental Health," publication of the American Association for the Advancement of Science, No. 19, publication committee H. Trendley Dean and Paul C. Kitchin, 1942, be made a part of the record of the committee.

Dr. HEDRICK. If no objection, they may be admitted.

(The pictures referred to are herewith inserted.)

Mr. KLEINFELD. Dr. Doty, you say on page 3 of your statement that—

> At approximately the same time that fluoride in water supplies was determined to be the cause of dental fluorosis, dental scientists were reporting findings that the incidence of dental decay appeared to be significantly lower in persons afflicted with dental fluorosis.

Did those things occur at the same time?

Dr. DOTY. That is intended to represent—beg your pardon—it is approximately the same time period.

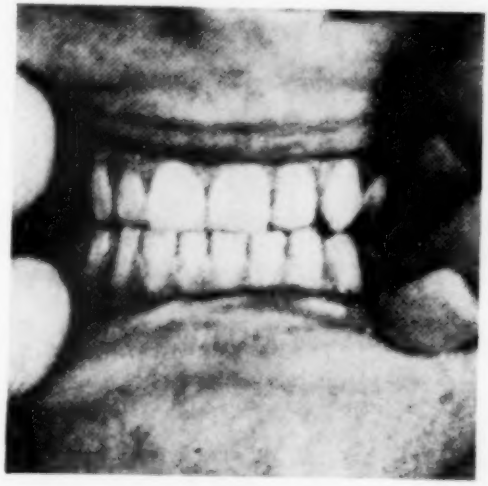
I might point out that the condition known as dental fluorosis was recognized many years before the cause was recognized.

Mr. KLEINFELD. In the same paragraph on page 3 you state:

> Where objectionable dental fluorosis occurred, the concentration was ordinarily found to be several parts per million, in some cases up to 15 parts per million.

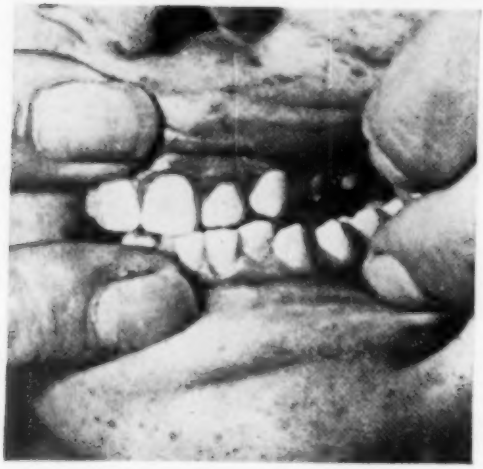
Isn't it a fact that objectionable dental fluorosis has been found in communities where the water contains less than several parts per million?

Dr. DOTY. That is my belief; no. Again reflecting the opinions of the groups with which I have been associated, I do not believe that

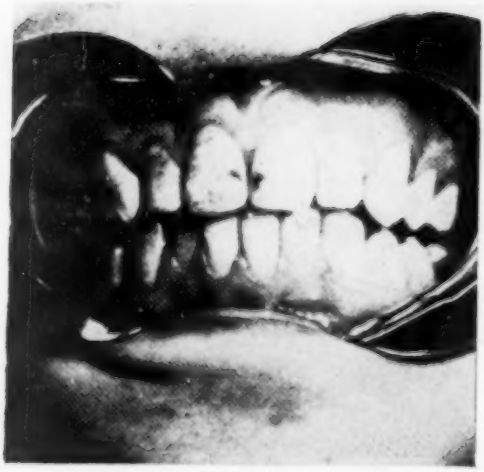


Normal.

Questionable.



Very mild.



Mild.

Moderate.

Severe.

there has been any significant observance of objectionable fluorosis at levels much below 2 parts per million.

I might point out, however, that from my acquaintanceship with the types of work that have been done, there are a number of factors that need to be considered in connection with this particular problem. However, I think that it is reasonably safe to assume that at levels below 2 parts per million there will not be any substantial amount of objectionable fluorosis.

Mr. KLEINFELD. In this table 11 to which we have referred, there is the city, for example, of Kewanee where the water supply had 0.9 part per million, and in that city 123 children were examined. 65 were found to be normal, 43 questionable, 13 very mild, 2 mild. That is in a concentration of less than 1 part per million of fluorine; is that not correct?

Dr. DOTY. I believe that the reported figure for the Kewanee water supply is somewhat less than 1 part per million. I do not have the table immediately in front of me, but I assume that is correct.

Mr. KLEINFELD. In the city of Marion, Ohio, where the concentration was 0.4 part of fluorine per million, 263 children were examined. 151 were found to have normal teeth, 96 questionable mottling, 14 very mild mottling, 2 mild mottling. That is considerably less than even 1 part per million; is that not correct?

Dr. DOTY. Obviously, 0.4 part per million is lower.

I might comment at this point, that the very fact tht some of these spots or mottling, or whatever—I prefer not to use the word "mottling" because mottling has been so definitely associated with fluorosis. The two are, of course, not necessarily identical. But there are reports of the finding of spots on the teeth of children in areas which are essentially free of fluorides.

I do not believe that the articles to which you refer are intended to indicate that in every instance those observed spots are truly fluorosis. But I think that they are the record to the best of the ability of the observers of such conditions as they observed in those areas.

Mr. KLEINFELD. Well, then, you are saying that the observer in this case, apparently the Public Health Service, just doesn't know whether it is mottling caused by dental fluorosis or not?

Dr. DOTY. As far as I am aware, the recognition of the condition and its description as fluorosis is dependent upon several factors: The actual appearance of the condition itself, and the association of that condition with an intake of water containing fluorides. I think that similar spots or appearances on teeth may be found in areas where the water is completely or essentially free of fluorides, and it may not always be possible for the observer to differentiate between the two.

Mr. KLEINFELD. Well, then, are we to rely on the statistics and experiences in localities which have natural fluorine in their water or not?

Dr. DOTY. I would say that there is a high degree of reliance to be attributed to such figures. If there is any error, I think it is on the side of reporting more than might actually have been caused by the fluorides.

Mr. KLEINFELD. You would recommend that we be conservative in that respect, would you not?

Dr. DOTY. Obviously.

Mr. KLEINFELD. On page 3 of your statement, Dr. Doty, the last sentence of the second full paragraph on that page, you say:

> Today dental scientists safely anticipate a reduction of 60 to 65 percent of the number of cavities ordinarily expected in a given age group, if that group has been drinking fluoridated water during the dental formative years.

Just what do you mean by "safely anticipate"?

Dr. DOTY. That is based upon the, shall I say, average, or the experience generally in the number of epidemiological studies as well as the number of direct addition studies which indicate that those are approximate figures representing the lower amount of caries that may be anticipated in the fluoridated as compared to the fluoride-free waters.

Mr. KLEINFELD. Would it be a sound statement to say at this time that the employment of sodium fluoride in drinking water will reduce the incidence of dental caries by 65 percent if 1 part per million of fluorine is added to the water?

Dr. DOTY. Where 1 part per million of fluorine is present in the water and is utilized by the children during their dental formative period, I would say this is a reasonably conservative estimate.

Mr. KLEINFELD. And on what is that based?

Dr. DOTY. Based, as I say, upon the actual findings on epidemiological studies in areas where fluoride is in the water, plus the correlation of those findings with the findings in areas where the fluoride had been directly added to the water.

Mr. KLEINFELD. So in this case you are relying quite a bit on the localities where natural fluorine is present in the water; is that correct?

Dr. DOTY. I think that that is so obvious and so obviously desirable that no other assumption could be made.

Mr. KLEINFELD. And you are relying also on the pilot study cities which are presently conducting experiments with the addition of sodium fluoride to the water?

Dr. DOTY. That is correct.

Mr. KLEINFELD. Which ones have reported a 65 percent reduction of the incidence of dental caries where 1 part per million has been added?

Dr. DOTY. As I indicated to you, I said the correlation of the findings in the areas where it is added to the water supply with the findings of the epidemiologic surveys.

The point is that this total anticipated benefit is not derived in 1 or 2 or 3 years, it is derived when the children use this water during the entire formative period of the teeth. However, from the epidemiologic studies, it is apparent that the children begin to derive these benefits at an earlier age, having had the use of the water throughout all of these periods of time, and the results obtained at the various stages in these direct addition experiments have been the results to be expected at those particular time intervals. In other words, those results correlate with the results as found and predicted from the epidemiologic studies.

Mr. KLEINFELD. Dr. Doty, on page 4 of your statement you say:

> Slight adjustments of the ratio of 1 part per million may be desirable according to the quantity of water normally imbibed per individual in a particular geographical region.

How would you define "slight adjustments"? What would they amount to?

Dr. DOTY. Well, here again you are asking for a statement from an individual who is not an authority on that particular phase. I would say, however, that those adjustments probably would not be expected to exceed one-half part per million.

Mr. KLEINFELD. Can you say definitely, if you know, whether these adjustments have definitely been determined for particular localities in this country?

Dr. DOTY. You mean the evidence in regard to that or whether or not actual fluoridation procedures?

Mr. KLEINFELD. Whether the proponents of the fluoridation of public drinking water have determined for particular localities what slight adjustments are necessary for those particular localities?

Dr. DOTY. There is some evidence in that regard; yes, sir. Dean has shown from studies in certain areas, which I hope that he has brought before you already, that the benefit may be derived—the studies were carried out in Georgia, I believe—that the benefits may be derived from the presence in the water supply of a concentration less than 1 part per million. The presumption is, I believe, that that is due to the fact that the amount of water consumed by the individuals there is somewhat higher on a per-day basis than in the other climate.

Mr. KLEINFELD. Would it be safe or advisable to proceed with fluoridating the water of a particular city unless that ratio had been fixed with some certainty, that slight adjustment made?

Dr. DOTY. It would be my impression that the proper authorities who are controlling this procedure in the various municipalities would very carefully examine all existing data, and it would be my impression that they would tend to be conservative in their estimate on the amount to be added in such an area.

Mr. KLEINFELD. What data would they examine?

Dr. DOTY. I think that they would examine all data pertaining to the water intake of the individuals and such studies as that to which I have just referred, of Dean in Georgia.

Dr. HEDRICK. Do you feel all right, Dr. Doty?

Dr. DOTY. I would rather go ahead and finish.

Dr. HEDRICK. You do not feel too well, though, do you?

Dr. DOTY. No; I have been sick today.

Dr. HEDRICK. Do you feel like finishing?

Dr. DOTY. I would like to serve the committee as far as I can.

Dr. HEDRICK. All right, go ahead.

Mr. KLEINFELD. I will try to make it as short as I can.

On page 5, Dr. Doty, you say:

> It has also been shown that the elimination of ingested fluorine by way of perspiration, urine, and feces is practically complete when the fluorine ingested does not exceed 4 to 5 milligrams daily. A survey of the amount of fluorine in urine specimens of high school boys and young selectees shows that the concentration of fluorine in the urine is almost identical with the concentration in the drinking water up to about 4.5 parts per million.

Now you say that the elimination is practically complete. Would you please explain that?

Dr. DOTY. As I recall, in the experiments of McClure, balance studies, I believe that they accounted for more than 90 percent of the ingested fluorides in the excreta.

Mr. KLEINFELD. Dr. Doty, are you familiar with various statistics indicating mortality rates, morbidity rates, and similar figures?

Dr. DOTY. I would not pretend to be an expert in that field.

Mr. KLEINFELD. For example, this morning the Public Health Service gave us two attachments, attachment C and attachment D. Attachment C was labeled "Cancer morbidity and mortality rates per 100,000 for cities with varying concentrations of fluorides in the public water supply." Different States were taken in this attachment, and the mortality rate given for 2 years—I believe there are about six cities in four States picked, and the mortality rate for 100,000 of the population was given. Comparison was made with the amount of fluorine in the drinking water of those cities and States. I want to show you this attachment C and ask you whether those figures are statistically significant.

Dr. DOTY. As I have indicated, I am not an expert in the field of vital statistics. I might suggest that one of the individuals included on the list here, O. K. Sagen, of the Division of Vital Statistics and Records, Springfield, Ill., would be an individual better qualified to render an authoritative opinion to the committee on that subject.

Mr. KLEINFELD. For example, using these figures for what they are worth, someone has sent to this committee excerpts from the United States Bureau of Vital Statistics—"Crude total death rate per 100,000." They give these figures, for example:

They give the New England area, which apparently does not have fluorine naturally in its drinking water, and say that apparently 2.6 deaths per 100,000 in New England occur from appendicitis. In the Mountain States, where apparently some fluorine does occur naturally, 8.1 people out of 100,000 died from appendicitis. Would those figures mean anything to you at all?

Dr. DOTY. I would think that all vital statistical data must be analyzed carefully and by experts who are trained to recognize the points where errors might creep in.

Mr. KLEINFELD. In other words, would it not be entirely illogical to say that because 2.6 people in New England of 100,000 died of appendicitis and New England did not have naturally fluoridated water, and 8.1 people out of 100,000 in the Mountain States died from appendicitis and the Mountain State people had naturally fluoridated water, therefore fluorine had something to do with appendicitis?

Dr. DOTY. I am afraid I got a little bit lost in all of that.

Mr. KLEINFELD. I will just ask one more question, Doctor.

Mr. JONES. Mr. Chairman, this man said he is not an expert on that. I submit that Mr. Kleinfeld keeps pressing him for an opinion which would not amount to much if we did get it. I think we are just wasting time going ahead with such a line of questioning. He does not pretend to be a competent witness on this, so let's get someone who is.

I am not criticizing Dr. Doty, because that is not his field.

Mr. KLEINFELD. Dr. Doty is a scientist and he is testifying. I asked him whether he could give any opinion on these statistics. If the committee doesn't want to hear it, it is quite all right.

Mr. JONES. You were also trying to infer because they have fluorine in the water out in the Mountain States they have appendicitis.

Mr. KLEINFELD. No; I am not.

Mr. JONES. I am trying to say Dr. Doty has told you a lot of other factors have to be taken into account—the number of doctors in the community, for instance.

It seems to me we are putting these people on, trying to persecute these people because they have given you their findings, and you have taken an attitude here that is wrong. I do not like the line of testimony or questioning that we have followed here today at all.

I am sorry to have made this outburst.

Mr. KLEINFELD. No further questions.

Dr. HEDRICK. No more, Mr. Kleinfeld?

Mr. KLEINFELD. No.

Mr. JONES. I want to make a statement here. I think that we have followed a line of questioning, Mr. Chairman, and we have tried, it appears here today, the line of questioning because the Public Health Service has made a recommendation. And it seems that in this committee there has been, apparently, an attempt to pit the Public Health Service against the Food and Drug Administration. I think that some of us, at least, have been prejudiced in that. I hope that I am not prejudiced in it, and I would like to see fairness prevail.

I think that what we have done here—here, one member of our committee introduced a bill asking for fluoridation of water, or at least proposing it, and apparently has taken a different position now. I think we have had the most competent witnesses before us. I think they have given us some valuable evidence.

As far as the fluoridation of water is concerned, personally I am not committed one way or another. I think that what we have had here today, they have to be weighed as to whether we consider the benefit to be derived from the fluorine in the water in reducing the caries in teeth—that would have to be balanced—against any discoloration that might appear on the teeth.

I think that is going to be a matter for the public or the public officials to decide.

I would like to ask you, as a scientist, Dr. Doty, is the amount of fluorine that we would ingest in food such that it would have the same effect as the amount of fluorine ingested in water?

Dr. DOTY. There may be some presumption in that regard, but I do not think that it has been adequately tested.

Mr. JONES. In other words, you don't know?

Dr. DOTY. We do not know, because there are not adequate experiences the way there is in fluoride in water.

Mr. JONES. Would that be the reason that the American Dental Association has not made a recommendation of addition of fluorine in foods?

Dr. DOTY. That is correct, because of the conservative policy.

Mr. KLEINFELD. Mr. Jones, may I say that if it is the view of the committee that the question has been unfair or hostile, I will withdraw from further questioning on this or any other subject.

Mr. JONES. I am just expressing my personal opinion on this. Every other member of the committee has the right, and I am sorry the whole committee is not here, as I would like to express that before the whole committee.

Dr. HEDRICK. Mr. Horan.

Mr. HORAN. I would like to thank Dr. Doty for appearing here today.

I want to make my own position clear, because I might be one of those that could be accused of pitting the Public Health against the Food and Drug. I am not doing that.

Dr. HEDRICK. You don't look well to me, Dr. Doty. Have you any fluorine in the great State of Washington, Mr. Horan?

Mr. HORAN. We import it. [Laughter.]

I want to say this: In the orderly management of our governing bodies I feel that we must first have those capable of finding the facts. I am sorry myself that I did not get a chance to question Dr. Dean further this morning, because I think he is our great repository of information in the field of fluorine and its appearance in nature and industry and in medicine. I wanted to develop findings of its use in nature and findings of its use in industry in the problems that have grown through the years, and to superimpose upon that the problems of finding the tolerance that we could use safely in the management of our municipalities and our cities and society in general. But I did not get a chance to do that.

I did ask you to amplify your remarks, Dr. Dean. I think we would be remiss if we did not have further information from Dr. Dean and place him on the stand.

I say that, I think, with lack of levity, because he can answer these questions, and obviously Dr. Doty has excused himself as a qualified witness in this regard. He is merely passing on to us the findings of a long list of scientists of which Dr. Dean is one.

If we want to inquire deeply into this, we had better get the man who can answer those searching questions, in my opinion. After we have found those, then I would like to say to the Food and Drug or to our municipalities: Here is what should be done: I assume that in the summertime if you do fluoridate your water, you put less in it; and in the wintertime, if you fluoridate your water, the tolerance can be raised.

Those are things that intrigue me. I would like to know the answers if you are going to fluoridate.

Now, obviously, it has been accepted by a lot of our municipalities, and upward of 4 million people, I guess, drink artificially fluoridated water. Is that true?

Dr. DOTY. I do not have the immediate figures here. There is something over 200 municipalities.

Mr. CONWAY. I might add that a survey was done by the American Dental Association through its components and constituent societies for that information, and it was reported to the association that about 214 municipalities have already fluoridated.

Mr. HORAN. We have a problem here that deeply affects me, because I believe in the autonomy of municipalities. We are very practical to have that autonomy.

My problem then resolves itself—what safe advice can the Federal Government give to municipalities who are fluoridating the water?

Mr. CONWAY. The American Dental Association believes firmly in that stand too. In fact, that is inherent in our resolution. We merely recommend to our component and constituent societies that they take steps, and we recommend to them how they should do that. In other

words, they must work through the local dental society and under the guidance of responsible health authorities. We make the recommendation qualified in that way.

Mr. HORAN. Involved here also—and this is not directed to you, Dr. Doty, it is directed to Dr. Dean—I do not want in any way to try the very reliable and very responsible chemical companies here. So in amplifying your remarks, Dr. Dean, when we discuss the effect on the bone structure of the body of miners who mine it, and those who process it, and those who may have bagged and may have transported it—and you stated there were adverse effects, but further studies have shown on getting away from fluorine they recover. I want to know what has been done by those industries to make sure that that did not recur, because I have every faith in their responsibility.

And we want the Public Health Service to exist, and we want the Food and Drug to exist to make sure that our society profits by acquired or accumulated knowledge, and that we make life longer and life safer by proper findings of fact and a proper application of fact after they have it.

The only trouble we have here on this fluoridation question is, I think, it has moved out of the field of medicine into the field of politics. It looks that way to me. If it is going to be in the field of politics I do feel responsible in order to protect 214 municipalities from any Federal interference. I want to pay my respects to you, Dr. Dean, as a man in the Public Health Service who has done a good job.

Mr. CONWAY. Might I say something? The association selected Dr. Doty because they believed he was well qualified in the field of biological and physiological aspects of the fluoridation question. In other words, the association felt this committee was more interested in the safety factors, and that is why Dr. Doty was selected, he being a qualified expert in the field of biochemistry and physiology.

Mr. HORAN. This committee, of course, exists to find these facts by mobilizing the wisdom of the Nation on these facts, and in most cases we have been very happy with the witnesses.

I want to say for Mr. Kleinfeld that I think he has been reasonably good, but I think you are a little bit "hep" like some people here in Washington, Vincent, on this fluoridation thing. It is a big thing in the papers and the papers have been playing it up, and it is intriguing. I know that. But usually you have been pretty fair.

I am inclined to agree with Paul today that you were a little prosecuting on some of these boys, and that is not what we exist for.

Dr. HEDRICK. Is that all the questions?

Mr. HORAN. That is not a question.

Dr. HEDRICK. Dr. Doty, I would be glad to know what is the largest amount of fluorine found in water normally that is used for drinking purposes in this country and in what kind of city is it used?

Dr. DOTY. At one time the town of Bauxite, Ark., was using a water supply [halting]——

Dr. HEDRICK. Don't bother about answering if you do not feel well enough.

Dr. DOTY. (continuing). Found to contain 14 parts per million or slightly higher.

Dr. HEDRICK. Fourteen?

Dr. DOTY. Yes. They are not at the present time using that water supply.

Dr. HEDRICK. Why did they quit it?

Dr. DOTY. Because of the mottled enamel.

Mr. HORAN. There is a nurse on the floor and I think we should call her, Camille.

Dr. HEDRICK. Mr. Kleinfeld, anything else?

Mr. KLEINFELD. No.

Dr. HEDRICK. The committee will stand adjourned.

(Whereupon, at 4:35 p. m., the committee was recessed to reconvene at the call of the Chair.)

CHEMICALS IN FOODS AND COSMETICS

TUESDAY, MARCH 4, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE
USE OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74, and H. Res. 447, 82d Cong., 1st Sess., continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d Sess.), at 10 a. m., in room 445, Old House Office Building, Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney of New York, Hedrick of West Virginia, Abernethy of Mississippi, Jones of Missouri, and Miller of Nebraska.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will come to order.

Call the first witness, Mr. Kleinfeld.

Mr. KLEINFELD. Is Dr. Porterfield here?

Dr. PORTERFIELD. Yes.

Mr. KLEINFELD. Please take the stand.

The CHAIRMAN. Remain standing, Doctor. Your name and address?

Dr. PORTERFIELD. John D. Porterfield, director, Ohio department of health, Columbus, Ohio.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF JOHN D. PORTERFIELD, M. D., SECRETARY-TREASURER, REPRESENTING THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS

Mr. KLEINFELD. Dr. Porterfield, where did you receive your degree of Doctor of Medicine?

Dr. PORTERFIELD. Rush Medical College of the University of Chicago.

Mr. KLEINFELD. In what year?

Dr. PORTERFIELD. Nineteen hundred and thirty-eight.

Mr. KLEINFELD. Generally what has your professional career consisted of since that time?

Dr. PORTERFIELD. I have worked in clinical medicine, in mental hygiene, and most particularly in public health administration. I have a degree of master of public health from Johns Hopkins School of Hygiene and Public Health, 1944, and have been since 1947 the

director of health of the State of Ohio. I have been for the last year and a half the secretary-treasurer of the Association of State and Territorial Health Officers.

Mr. KLEINFELD. And the statement you have is the statement of the Association of State and Territorial Health Officers?

Dr. PORTERFIELD. Yes, sir.

Mr. KLEINFELD. Will you please read your statement.

Dr. PORTERFIELD. May I express my appreciation to the committee for extending its hearings on the question of fluoridation of public water supplies and for affording me the opportunity to present the views of the Association of State and Territorial Health Officers and the basis for such views. Frankly, at the time I requested this privilege I was somewhat puzzled by the committee counsel's advice that the association's position had been made a matter of record, and that rather than appearing before the committee the association representative should file a statement. The puzzlement came from learning the published list of witnesses which the committee had initially invited to testify. It seemed unusual in the development of objective evidence on this question that those most responsible for judgment on these matters in the several States should not be solicited for a report of their experience.

I think it desirable at the outset of my testimony to outline briefly the position of a State health officer. As the executive responsible in his State for extensive and comprehensive programs of public health and preventive medicine, he is charged with the necessity of knowing a very great deal about a great many things.

The health and the lives of millions of citizens depend to a great extent upon his knowledge and upon his judgment. The daily realization of this sobering responsibility naturally tends to make him conservative and to condition his judgment upon a careful evaluation of the advice, recommendations, and evidence which are presented to him.

Now it seems to me obvious that a State health officer in making his decisions must depend heavily on the old saying that the next best thing to knowing is knowing where to find out. He cannot be a complete expert in every field in which he is concerned. He depends heavily therefore, upon the staff of qualified experts in his department and upon those recognized scientific groups which his experience has shown him are able to give him the advice he needs. If he is an expert, it must be in his ability to know whose advice to take. He must know whether his advisers have competence in the particular field, whether they are affiliated with an organization or institution of high integrity and, finally, whether the recommendations made are based on reasonably adequate evidence. The record and reputation of this association, composed of the chief health executives of all the States and Territories of the United States, is understandably, therefore, a conservative one, and it is considered by those with whom it deals as being cautious in its development and adoption of policies on matters of health.

It is not my purpose here to review in detail the extensive research reports which have been made since Crichton-Brown first suggested in 1885 in England that fluorine was an inhibitor of tooth decay. The statements or reports of the United States Public Health Service and the National Institute of Dental Research, of the ad hoc committee on

fluoridation of water supplies of the National Research Council, and of other competent bodies have been or will be, I hope, made a part of the committee's records with appropriate expert explanations.

Too voluminous for any one record, and for that matter never collected in one place, are the many considerations given in various individual States by health department personnel to the questions of effects on human health and on teeth of high concentration of natural fluorides in water supplies, of the high incidence of dental caries in areas with water supplies containing relatively no fluorides, and over the last 6 years of the effect of artificial water fluoridation. For instance, in Ohio, for many years the State health department in its mobile trailers has examined the teeth of approximately 150,000 school children a year and has found that as a general average 88 percent of those examined have dental caries. Not in minor degree but with an average of six carious teeth per child. Also for many years in Ohio we have checked the natural fluoride content of public water supplies. We have noted the facts that we do get mottled enamel but lessened caries incidence in populations drinking waters with high fluoride content, that we do not get mottled enamel but do get higher caries rates in populations drinking fluoride-free water, that the optimal balance between as little and as mild mottled enamel as possible and as great a reduction of caries incidence as possible is achieved at water fluoride levels coinciding very closely with those findings which have been published. We have observed from time to time the comparison of death rates from all causes and from selected causes between those areas with up to three parts per million of fluorides in the drinking water—Ohio's strongest concentration—and those areas with none, and have found no significant differences.

This sort of thing has been done in many of the States and published in some. It constitutes a background for the fact that in October 1950, the Association of State and Territorial Health Officers considered and adopted by vote of the total membership a resolution approving the artificial fluoridation of public water supplies for the partial control of dental caries, where the medical and dental professions concur and where communities can meet the standards of the State health authorities. The association since that date, with continuing attention, has found no reason to reconsider that position.

I would call your attention to the conditions of approval. It was the intent—and it is in the policy of the State of Ohio for one—that local physicians and dentists would have to concur in this judgment and thereby would be alerted to recognize any possible medical or dental reason which might arise making fluoridation undesirable. It was the intent—and it is the requirement in at least 43 States to my knowledge—that such program can be installed only where adequate facilities and competent personnel are available for the actual fluoridation and its continuing control.

It must also be pointed out that the determination to fluoridate a water supply rests with the community. Our approval is in no way mandatory legislation and no such program is initiated in any community until the governmental representatives of the community determine it shall be done and meet the conditions imposed.

Even in the study communities—Grand Rapids, Newburgh, Evanston—all official parties had to agree before the investigations were begun. Such agreement was made after it had been determined that

there was no danger to the population in carrying out these studies. On the evidence to date, there is no reason why they should be stopped but there is now evidence that the program should be continued.

One last point. While the substantial burden of investigative reports show a safely wide margin between the amounts of fluoride recommended for caries control and the amounts which will cause acute or chronic fluoride poisoning, it is true that the caries-controlling concentration approaches that producing mild mottling in a small percentage of individuals. I do not think this constitutes a valid objection to the proposal. The mildest mottling is apparent only on skilled clinical examination. Even in the occasional case where mild mottling might be more visible, it could be objectionable only on esthetic or cosmetic grounds. On the other hand, caries formation is objectionable on the grounds not only of esthetics but of health. If I had to choose between 10 percent of the community's children having mild mottling and 88 percent of them having extensive caries I would unhesitatingly choose the mottling. And I have no doubt that I speak for all the State health officers in making that choice. For that matter, as a father of two appearance-conscious teen-agers, I have no hesitation in making the same choice. Nor, they assure me, would they.

In conclusion, may I reiterate that I make no attempt to provide the committee with elaborate technical data in explanation of the stand of the Association of State and Territorial Health Officers. These data are available from many persons directly engaged in the fluoride studies. The State health authorities, recognizing their responsibility not only to protect the public health but to promote the use of effective disease-control practices, after review of the evidence, have seen fit to endorse and recommend controlled water fluoridation for the partial prevention of tooth decay. The association took due cognizance of the alleged hazards of this practice and found no supporting evidence. The association is seriously concerned with the kind of information given credence in this hearing and urges that extreme care be used in weighing the evidence which in the view of the State health authorities of the United States is overwhelmingly in favor of the general use of controlled fluoridation of public water supplies.

The CHAIRMAN. Will you give me the authority for the last sentence: "The Association is seriously concerned with the kind of information given credence in this hearing and urges that extreme care be used in weighing the evidence."

Did you contact every other member of the association? Did you have a vote on this?

Dr. PORTERFIELD. During the time, sir, that the association is not in its meetings of total membership, there is an executive committee which acts for the association and is usually under fairly careful instructions as to its actions. This was discussed with the majority of the members of the executive committee who were concerned at the first publicity they saw concerning it.

The CHAIRMAN. Tell us more about that. Is there any objection to the people who have been called here as witnesses before this committee?

Dr. PORTERFIELD. No, sir.

The CHAIRMAN. Do you object because their opinions do not happen to agree with the members of the association?

Dr. PORTERFIELD. No, sir.

The CHAIRMAN. Then give us the reasons for this statement. This is a prepared statement. You have had an opportunity to think of it.

Dr. PORTERFIELD. The objection was in the face of the possibility on the first publicity which came out, sir, that these witnesses which had been invited were the only ones who would be invited.

The CHAIRMAN. Did you find that to be a fact?

Dr. PORTERFIELD. Without knowing what causes changed it, it is not now a fact; no, sir.

The CHAIRMAN. It is not now a fact?

Dr. PORTERFIELD. That is correct.

The CHAIRMAN. Then you were unduly apprehensive at that time; is that correct?

Dr. PORTERFIELD. I was apprehensive. I do not know how unduly.

The CHAIRMAN. Have you or your association ever conducted any controlled experiments to show the effect of fluorine on teeth?

Dr. PORTERFIELD. The individual members of the association in their separate departments have from time to time done studies of that sort, yes, sir, as far as the effect of fluoridation of water or the presence of fluorine in water.

The CHAIRMAN. Will you elaborate on that? Give me a specific example of what they have done and over what period of time.

Dr. PORTERFIELD. Well, in the Ohio Department of Health, which has been referred to briefly in the statement, we have, over a period of approximately 10, 11 years, done examinations of school children in the communities of Ohio. The data collected in the examinations have been placed on cards and collected over a period of time.

The CHAIRMAN. Have you filed a report on that?

Dr. PORTERFIELD. Published?

The CHAIRMAN. Have you published a report?

Dr. PORTERFIELD. Not in the literature; no.

The CHAIRMAN. Do you not think that if you have all that information you should bring it to the attention of this committee by either filing a report or giving the benefit of that information to us?

Dr. PORTERFIELD. I would be very happy to, sir, but I could not do that in the period of time that I had.

The CHAIRMAN. Do you feel that there should be additional information on this subject? Do you feel that you have sufficient information now to say without any qualification that fluorine should be added to water in a limited quantity?

Dr. PORTERFIELD. It is my personal opinion and the opinion of the association that sufficient evidence has been collected and published to warrant the addition of fluoridation to water for the partial control of dental caries.

The CHAIRMAN. Just what amount of fluorine would you say is safe?

Dr. PORTERFIELD. I would say approximately 1 part per million. It would have to vary depending upon local conditions.

The CHAIRMAN. Are you familiar with the method of mixing the fluorine in water?

Dr. PORTERFIELD. I have had it described to me, sir, by my engineers. I would not be able to do it myself, no.

The CHAIRMAN. And you are absolutely satisfied that the amount can be controlled to 1 part per million?

Dr. PORTERFIELD. Within such limits of tolerance as would not have any effect; that is right, sir.

The CHAIRMAN. You believe it can be?

Dr. PORTERFIELD. Yes, sir.

The CHAIRMAN. We in Congress are accused of many things. Now there is great objection to the socialization of medicine, particularly by the medical group, and one or two have brought to my attention the fact that this is just getting our feet wet, so to speak. Have you any thoughts on that subject? It is claimed that this is mass medication. There are some religious groups who object to it. Have you discussed this phase with members of your association?

Dr. PORTERFIELD. Those discussions were carried on among members of the association before the association took its action; yes, sir. As far as medication is concerned, it was our feeling that this is rather preventive than treatment, and therefore there does not follow much of the problems that must follow in a mass medication. It has to do not with the treatment of caries or the cure of a carious condition, which it could not do, but with the prevention of it, in the same way that we have nutritional programs in most of our State health departments in which we recommend certain diets, certain practices on the part of homemakers, which is not treatment but which does prevent disease.

The CHAIRMAN. Are you satisfied in your mind, and the members of your association, that this is not the beginning of so-called socialization of medicine? Is it not a trend in that direction?

Dr. PORTERFIELD. That has been the subject not only in fluoridation programs but in most of our programs, sir—the question of how much socialization or how much governmental assumption of activity our programs carry on. While the association has never issued a positive statement with respect to any of the Federal proposals which are grouped under the title "socialized medicine," it is my personal opinion, and I am sure that almost without exception it is the opinion of the membership of the association, that this is not socialization of medicine as that term is ordinarily defined, and we would not be partial to it from that point of view.

The CHAIRMAN. Rather endorse it than object to it?

Dr. PORTERFIELD. I do not follow that.

The CHAIRMAN. You endorse this practice rather than object to it?

Dr. PORTERFIELD. Yes.

The CHAIRMAN. Mr. Kleinfeld?

Mr. KLEINFELD. I have no questions.

The CHAIRMAN. Dr. Miller?

Dr. MILLER. Dr. Porterfield, it says here "statement submitted on behalf of the Association of State and Territorial Health Officers." Are you a health officer?

Dr. PORTERFIELD. Yes.

Dr. MILLER. What State do you represent?

Dr. PORTERFIELD. The State of Ohio.

Dr. MILLER. The State of Ohio?

Dr. PORTERFIELD. Yes, sir.

Dr. MILLER. How long have you been a health officer there?

Dr. PORTERFIELD. Since 1947.

Dr. MILLER. I see. I was State health officer in Nebraska——

Dr. PORTERFIELD. So I understand.

Dr. MILLER. Eleven or 12 or 13 years ago. So I am not unfamiliar with the methods used by the State health departments and also on the national level of putting pressure on little fellows like you and me down at the State level. I had a lot of pressure put on me.

For instance, when we were ready to put on an immunization program in Nebraska we got into quite a battle between the public health people and the Children's Bureau as to who should pay for it. Of course, being a State health officer I was looking for all the money I could get, and the fellows that offered the most money we accepted. You do that too. And then they wanted to tell us how to do that program. So I am not unfamiliar with the pressure tactics on the higher level that are put down on the State as to dangling money before them to do these things.

Now there are 48 State health directors and one from each of the Territories, is that right?

Dr. PORTERFIELD. Yes, sir.

Dr. MILLER. Did you have a meeting, and if so, when, relative to recommending fluoridating water? Did you do that as a group or did that come down from a national level?

Dr. PORTERFIELD. If I may recount, sir, within the past 10 years—and I guess since you were State health officer—the conference of State health authorities with the Surgeon General of the Public Health Service and with the chief of the Children's Bureau has continued, but in 1942 the State health officers formed the Association of State and Territorial Health Officers, an independent, voluntary organization, obviously with restricted membership, but with no dependency on anyone but their own State government.

I may say that——

Dr. MILLER. Did you have a meeting then just of your group, or did it come from stimulation at the top to have fluoridation of water?

Dr. PORTERFIELD. No, sir. As a matter of fact the stimulation for consideration of this question came from one of our own group.

Dr. MILLER. And has your group made any examinations yourself as a group of what happens when fluorine is put in the water, or did you take the word of someone else like Dr. Arnold or Dr. Dean, who are in the Public Health Service? Whose word did you take? Did you have any individual scientific examinations as a group?

Dr. PORTERFIELD. The association as such did not conduct any surveys or investigations of their own.

Dr. MILLER. I see.

Dr. PORTERFIELD. The individual State health officers have done investigations both into the literature and into the practice in their State and have reported these at least to each other in these meetings. Some of them have been published, too.

Dr. MILLER. Yes. Well, the other day I pointed out some papers had been published by men in the United States Public Health Service. Dr. Arnold in his opening statement said this in 1948:

> At present it is deemed advisable to await results of these research projects before an unqualified recommendation for mass fluoridation of water supplies is made.

Now that was said in 1948.

So I was wondering just when the health officers got together and decided that fluorine in water should be recommended universally.

Dr. PORTERFIELD. The formal action was taken, sir, in our annual meeting on October 23 to 27, 1950.

Dr. MILLER. 1950?

Dr. PORTERFIELD. Yes.

Dr. MILLER. That is October?

Dr. PORTERFIELD. October 23 to 27.

Dr. MILLER. And you took the advice there, of course, of the people who were making these experiments in fluorine in water?

Dr. PORTERFIELD. Among others they were considered, and I think the question was discussed at least with Dr. Dean.

Dr. MILLER. Do you know who discussed the question with you at that time in your 1950 meeting? Did you have a paper on the subject?

Dr. PORTERFIELD. No, we had no paper on the subject. We would have consultants from the Federal Government at the time of the conference with the Surgeon General and at that time discussions of this sort could be carried on.

Dr. MILLER. Well, the stimulus then came from the Federal Government?

Dr. PORTERFIELD. No, sir, the stimulus first came by the submission of the question from one of our State health officers—the State health officer of Wisconsin, Dr. Carl Neupert.

Dr. MILLER. Let's proceed a little further with some of the statement, if the chairman will permit. I spent about 3 hours going over this last night and I would like to bring out some questions as to how efficient fluorine might be for adults.

Does the State and Territorial Health Officers Association recommend it is beneficial for adults?

Dr. PORTERFIELD. We have not taken a stand on that particular part of the question, sir. It is our general, but not formal, understanding that it has some effect in the direction of good on adults.

Dr. MILLER. But you are not sure about that?

Dr. PORTERFIELD. We have not had that proved to us, nor what amount.

Dr. MILLER. When it is used in children, at what age would you say the benefits might be?

Dr. PORTERFIELD. I would say at the completion of permanent dentition, sometime in the early teens.

Dr. MILLER. Dr. Arnold said in our testimony here in one of his papers that he had published, and I quote:

> A little, if any, effect can be expected in people who are more than 5 or 6 years of age when such fluorine therapy is instituted.

That was in one of his papers. Is that age a little low or a little high?

Dr. PORTERFIELD. I gather from that particular statement you read, sir, he was referring to the onset of fluoridation.

Dr. MILLER. Yes.

Dr. PORTERFIELD. In other words, as I understand the question, the fluoridation must be going on during the time when the teeth are forming and calcifying.

Dr. MILLER. Do you know how fluorine is eliminated from the body?

Dr. PORTERFIELD. From the body?

Dr. MILLER. Yes.

Dr. PORTERFIELD. Principally in the urine, sir.

Dr. MILLER. In the urine?

Dr. PORTERFIELD. Yes, sir.

Dr. MILLER. Do you know what effect it might have on somebody who has defective kidneys? A lot of people have kidney disease. What studies have been made by your group as to what effects fluorine might have upon the damaged kidney, since it is eliminated through the urine?

Dr. PORTERFIELD. There have been on the part of the association no studies directed immediately to any toxic effects upon diseased kidneys.

We have, instead, since each of our departments is pretty much involved in more things than we can afford to do, we have instead used our vital statistics divisions to compare morbidity and mortality rates between those areas which have fluorides in their water and those which do not. We have not found from those studies any evidence of an increased death rate either general or from specific diseases, including diseases of the kidney.

Dr. MILLER. You and I know as health officers you can prove most anything you want to by these statistical figures on morbidity and mortality. I have seen them used time and time again. I am not going to accept those figures as authentic at all.

What studies has your organization made as to what might happen to older people who have fluorine added to their drinking water?

Dr. PORTERFIELD. The association has made no direct studies on that question.

Dr. MILLER. That is what Dr. Arnold said when I asked him the question last week:

> You have not made any studies as to what it will do to older people outside of examination of the bony structure?
>
> Mr. ARNOLD. No, sir. I didn't get to complete our Bartlett study, Dr. Miller.

Then they did do some X-ray examination but nothing on the kidney.

For instance, fluorine is eliminated, as you say, through the kidney. There has been no study as to what might happen to a damaged kidney when fluorine is added to the water.

Now, doctor, I am a little disturbed about your last sentence there relative to, well—

> The association is seriously concerned with the kind of information given credence in this hearing and urging that extreme care be used in weighing the evidence, which in the view of the State health authorities of the United States is overwhelmingly in favor of the general use of fluoridation in the public-water supplies.

You do not doubt that the committee has a right to inquire into fluorine in drinking water?

Dr. PORTERFIELD. Not in the least, sir. We welcome that interest of the committee, and there were no implications in that statement beyond——

Dr. MILLER. You did not think that some witnesses who did not agree with you were not creditable witnesses?

Dr. PORTERFIELD. Not because they did not agree with us; no, sir.

Dr. MILLER. Doctor, the United States Public Health Service, you say, has done no examination as to what happens to older people.

Dr. PORTERFIELD. No, sir. Pardon me, sir. The association has not.

Dr. MILLER. Well, the United States Public Health Service also. I read Dr. Arnold's testimony and he said nothing had been done.

Dr. PORTERFIELD. I see.

Dr. MILLER. The United States Department of Agriculture made some examination as to what happened in brood sows. They recommended to the farmers that fluorine not be added to the water or feed of brood sows because it did something to the pigs that were unborn.

Dr. PORTERFIELD. Yes.

Dr. MILLER. Do you think it might be wise for the Public Health Service or some group of people to inquire what might happen to pregnant women and the unborn child when they are given fluorine? Do you think it is necessary to complete the examinations that have already been started on that subject?

Dr. PORTERFIELD. I do not think there is enough money, sir, from the Federal Government or any other source, to pursue all of the possible hypotheses that may be proposed for most of our programs. We have to screen them from the point of view of greatest probability, and since we can find no cause from the physicians nor the dentists nor the investigative scientist pointing to this, it would seem to us not of a high priority to devote money looking for something that has shown no suggestive indications.

Dr. MILLER. Would you say that the Agricultural Department went off on a tangent then when they investigated what might happen to pigs or brood sows?

Dr. PORTERFIELD. No, sir; I think there is a difference.

Dr. MILLER. It is all right to do it with pigs, but you do not want to do it with women. Is that the attitude you take?

Dr. PORTERFIELD. They have different objectives in mind, sir. There is more money available for matters that have economic value than there is for health.

Dr. MILLER. We had before the committee Dr. Hans H. Neumann of 1377 Kew Street, Hewlitt, N. Y., who gave some testimony. Do you know Dr. Neumann?

Dr. PORTERFIELD. No, sir; I do not.

Dr. MILLER. He qualified himself as being somewhat of an expert. He had a tremendous lot of experience in medicine all over the world, and presently I believe he is with Columbia University doing some research work.

In his testimony he says this:

> I am unable to give any opinion on the possible toxic effects of water fluoridation upon the general public.

He also says:

> Fluorine is excreted readily by the normal kidney. Possible toxic effects would occur rather in an age group in which renal impairments of various types are more common, that is, in the old-age group.

He is recommending there that a study be made upon older people as to what might happen.

Now Thursday we are going to have Dr. Ast before us, who is head of the Newburgh experiments in Newburgh, N. Y., and I notice Dr.

Neumann quotes him in his testimony. Let me read this one paragraph, Mr. Chairman:

To give examples of the wide range of illusion in caries estimation, I quote the Gottlieb impregnation method, which was described by its author, an outstanding scientist in the dental field, as reducing caries by over 60 percent, even 80 percent. This method was used throughout the country by a large number of dentists and was taught over many years. Recently, though, a study by Dr. Ast concluded in describing the method as worthless and it fell since in disfavor.

Do you know what the Gottlieb impregnation method was for teeth?

Dr. PORTERFIELD. No, sir; I don't.

Dr. MILLER. In other words, a thing that they recommended at one time as being universally good apparently has come into——

Dr. PORTERFIELD. Disrepute.

Dr. MILLER. Disrepute at this time.

Dr. Neumann said on the same day in his testimony:

Looking over the reports on the effect of experimental water fluoridation, beginning 1946 and before, their results are not by any means unanimously recommending the procedure. While the experiments in Newburgh, N. Y., Grand Rapids, Mich., and Sheboygan, Wis., induced the observers to great optimism, the authors of a report on the Evanston, Ill., study consider their findings far from conclusive and a study from Ottawa, Kans.—C. A. Scrivener—which began in 1946, was reported to have resulted in a deterioration of the dental condition of the children.

What I am trying to get at, Doctor: Experiments are going on in Newburgh. They were 10-year experiments. They still have about 5 years to go. There are some questions that have been unanswered in this experiment, and I am wondering what is the hurry to add fluorine to the water before we have the experiment completed at the Newburgh laboratory and others that are still going on. What is the hurry about adding fluorine to water?

Dr. PORTERFIELD. I would say this, sir: In the first place, the original proposition to have the Newburgh study go 10 years does not necessarily bind it to that time to produce its results. I do not know how much longer they feel they should go to get the number of statistics that they would like.

Dr. MILLER. Was it to prevent caries in teeth?

Dr. PORTERFIELD. Yes, sir.

Dr. MILLER. How much caries is prevented when you use fluorine in water?

Dr. PORTERFIELD. It depends on how much the children got before; but if they had none at all and began to get approximately 1 part per million of fluorine in their drinking water from birth on, it would prevent about 65 percent. In other words, it would be 65 percent less than there was.

Dr. MILLER. Do you know if there is any place in the United States or in the world where there is practically fluorine-free water, no fluorine in the water at all?

Dr. PORTERFIELD. Yes, sir.

Dr. MILLER. Do you know what the incidence of caries might be in those areas?

Dr. PORTERFIELD. Yes, sir.

Dr. MILLER. What would it be?

Dr. PORTERFIELD. It will run about six carious teeth in approximately 88 percent of the children on the basis of the Ohio studies.

Dr. MILLER. Let me read the testimony of Dr. Neumann. He has been all around the world. On this question of fluorine he said this:

At this point it may be added that many areas whose water is practically fluorine-free have very excellent teeth which further cautions in attributing too much consequence to fluorine.

Let me read further on that same subject.

Mr. ABERNETHY. He finds himself alone in that statement; does he not?

The CHAIRMAN. He is a man who has traveled throughout the world and observed teeth in every section of the world.

Mr. ABERNETHY. The fact remains that no one has agreed with him in that statement; have they?

Dr. MILLER. Yes, they have, sir. I will read something out of a book here on Europe—rather conclusive evidence if you want to accept it.

Doctor Neumann said this about kidneys:

How an individual with impaired kidneys is able to excrete the fluorine I do not know. And to my knowledge there is no such study. As impaired kidneys are more common in old people with arteriosclerosis or with hypertension, I believe that a similar study would be indicated.

Now you say there have been no studies made on arteriosclerosis or hypertension or those with impaired kidneys. That was your testimony and that is the testimony of the Public Health Service. There are some studies being carried on, but before those are completed you folks jump in and endorse the use of fluorine in water for everybody.

It is admitted it does not do any good after 7 years of age. It will not do us fellows up here any good at all and it might do some harm; but we are going to have mass medication to take care of the youngsters up to 7 years of age. Is that your attitude?

Dr. PORTERFIELD. My answer is we do not conceive of it as mass medication but rather preventive.

Dr. MILLER. What is your definition of medicine?

Dr. PORTERFIELD. Curative medicine.

Dr. MILLER. Do you not recognize preventive medicine, smallpox vaccination and injections to prevent diphtheria and typhoid? Isn't putting medicine in water a mass medication? I know you do not like that word, but it is pretty hard to get off that stump because it is medicine in water to prevent caries—preventive.

Dr. PORTERFIELD. I will accept it on that basis; yes, sir.

Dr. MILLER. Preventive medicine.

Dr. PORTERFIELD. In the second place, since we have not found in all of the areas in the United States where our engineering divisions have observed the presence of fluorides in more than 1 part per million, and sometimes considerably higher, any difference in the physical condition of the inhabitants of those communities, in the way of dying earlier or of having diseases or conditions in any greater degree than they do in other communities, we have then considered only the question of the dental problem. And we feel that if we do have the amount of caries that we have in our communities today, and if this device, which is the safest of which we can conceive, will reduce it in some degree, whether it be 30 percent or 65 percent, it is worth it without waiting for five more years of caries experience.

Dr. MILLER. If that were true, I think I would agree with you, Doctor. I think fluorine in water for children is fine. I agree with you.

I talked with the Surgeon General about it just before I came up here. He said, "I give my youngsters fluorine in water every morning in a tablet."

That is fine. That is the way to do it. I think every child ought to have it if he does not otherwise get a dose of it some way.

I do not know whether I want to take it in the morning or not. Maybe I do not need it. Maybe my kidneys are in trouble.

Here is what Dr. Neumann, relative to fluorine in water, said:

Although at this point I would also say that there are many areas without any fluorine in the water where the caries incidence is nil practically. So that it cannot be reversed and said that the fluorine in the water is essential for caries prevention. Perfect teeth can occur in areas without any fluorine in the water and are common, actually.

I could read you scientific citations here, hundreds of them.

Again Dr. Neumann said:

That means that in an area where fluorine is in the water the teeth may be 10 times worse than in other areas that are fluorine-free, depending on other factors which apparently influence caries more than fluorine.

Then he discusses the question of waiting for a while, as to whether he would rather wait.

I asked him about when we should start the experiments, and he said:

Well, I would rather at this point say that I would rather wait for a rather brief period of time and have some more definite opinions. I would say one thing: There are recommendations on the part of the American Dental Association and the American Medical Association and the National Research Council and by innumerable authorities, who all base their statements on each other's recommendations, and none of them really have made any research themselves. It goes down in the end all to the five studies that have been going on for several years. So if the American Dental Association adds anything for the Research Council, it all goes back to the same testimony and has no additional value.

I found that is true in going through all these papers—they were all a repetition. The dental group said one thing, the Public Health said the same thing in another paper, or the medical group. They are repetitious, they contain nothing new.

I also asked him this:

There are some experiments still being carried on, though, that have not been concluded; is that right?

Dr. NEUMANN. A number. None of them have been concluded.

Then coming over to the use of fluorine, Dr. Neumann said:

Tea has a very high content of fluoride—

I think you will agree with that.

Dr. PORTERFIELD. Yes.

Dr. MILLER (continuing):

and the highest content of any drink, of any food. The English are the biggest tea consumers, yet their teeth are among the worst, which is a contradiction I could never understand.

How would you explain that?

Dr. PORTERFIELD. How would I explain it, sir?

Dr. MILLER. Yes; the teeth of the English being so bad when they always drink so much tea that is loaded with fluorine.

Dr. PORTERFIELD. I think that is rather a difficult question to answer, because, as Dr. Neumann has said himself, there are a considerable

number of factors affecting the development and preservation of teeth, and I am not personally aware of what factors influence the English. Our recommendation has to do with conditions in the United States, including such things as diet, dental care, general nutrition, and general hygiene of people.

Mr. ABERNETHY. Then the answer to that is you do not feed infants on tea.

Dr. MILLER. Now with respect to topical application. If you are going to recommend fluorine in water, of course, there are a lot of people who do not have a communal water supply, people on farms and small towns. I think there are 175 or 180 towns now having generalized fluorine in their water. They will probably start it here in May in the city of Washington. How would you reach those people in the country so they would have fluorides in their water?

Dr. PORTERFIELD. That brings me back to another question that you asked before, sir, and that is the choice of this method for applying fluorides to developing teeth.

We are quite sure, from having done topical application of fluorides for a small number of years, that we would not be able to accomplish it in a high enough percentage of the population. There are not enough dentists, and in those States which permit it, there are not enough dental hygienists to apply to all of the population. Therefore, if we can take our municipal population which does have municipal water supply and care for them by this mass method of fluoridation, it will give the dentists and the health departments and those doing clinical work time to concentrate on topical application where it is not possible.

Dr. MILLER. How would you reach the farm people that do not have fluorine in the water—no communal water supply?

Dr. PORTERFIELD. One way we have tried in Ohio is on our dental trailers which stop at the various crossroads of Ohio. After the investigation of the teeth to determine their status, we do apply the topical fluoride treatment. It is rather difficult and quite expensive compared to fluoridation of public water supplies, but it is the only way we can reach them.

Dr. MILLER. Do you get the same effect from taking a tablet every morning, like Dr. Scheele gives to his children?

Dr. PORTERFIELD. I am not sure that is as effective as topical application after dental prophylaxis.

Dr. MILLER. Is it just as good to take a drink of water with fluorine in?

Dr. PORTERFIELD. I think perhaps, yes, if it is done frequently enough.

Dr. MILLER. In other words, you could do it?

Dr. PORTERFIELD. Yes, sir, as far as its effects on teeth is concerned, but I do not believe we could do it from the point of view of administrative practicality.

Mr. ABERNETHY. Will you yield there, Doctor?

Dr. MILLER. Surely.

Mr. ABERNETHY. Is the tablet method universally used?

Dr. PORTERFIELD. I do not think so, sir.

Mr. ABERNETHY. Is it costly?

Dr. PORTERFIELD. It would be more expensive than this other.

I think the real answer, however, is that anything which you leave to the initiative of the individual to use is used in a varying percentage, including, for that matter, the brushing of teeth.

Dr. MILLER. Do you know whether fluorine has increased in price since the Public Health Service has advocated its universal use?

Dr. PORTERFIELD. I have no knowledge of that; no, sir.

Dr. MILLER. You would not know how much the equipment has gone up?

Dr. PORTERFIELD. As far as we know on Ohio's experience it has not changed in price.

Dr. MILLER. Have you priced it recently?

Dr. PORTERFIELD. Yes, sir.

Dr. MILLER. Where does fluorine come from, sodium fluoride and other fluorine substances?

Dr. PORTERFIELD. I think the principal sources in this country are Illinois and Kentucky.

Dr. MILLER. What companies make and supply fluorides?

Dr. PORTERFIELD. I honestly don't know.

Dr. MILLER. You would not know that?

Dr. PORTERFIELD. No. Our engineers would, but I do not.

Dr. MILLER. You would not know whether the Aluminum Co. of America supplied it or not?

Dr. PORTERFIELD. No, sir; I don't know that.

Dr. MILLER. I want to read, Mr. Chairman, if you will permit, one paragraph into the record on experiments in England from Great Britain's Water Pollution Board—Summary of Literature, 1946–48. I will read one short paragraph on page 266 from Summary of Current Literature. It is by Wilson and Roberts and some other men in England.

> In an investigation to determine whether juvenile osteochondritis of the spine is related to the quantity of fluorine ingested as well as to poor nutrition, groups of boys aged 14–17 years from a public school and from the poorest quarters in Oxford and children from Launton, Oxfordshire, were examined. Oxford's water supply contains negligible amounts of fluorine, but the public-school boys came from different parts of the country, and the quantity of fluorine in their drinking water was not known; about a sixth of them showed some dental fluorosis. Both groups of boys had the same percentage, about 20 percent, of nonspecific spinal irregularities; the lesions were not severe. The children from Launton where the drinking water contains 1 part per million fluorine showed nonspecific spinal irregularities in 64 percent of the cases examined. The lesions were more severe than in the other groups. The Launton children were probably less well-nourished than the public-school boys, but no comparison of the relative nutrition of the Launton and Oxford children could be made with certainty. It was concluded that the osteochondritic spinal condition is associated with fluorine ingested or with some factor associated geologically with fluorine.

There are numerous articles here from England on the pollution of water, which refer to fluorine. This is one article I did want to put in the record. This was in 1948. With one part per million of fluorine in the water of Launton, 64 percent of the boys showed spinal injury, and they came to the conclusion that the spinal conditions was associated with the fluorine in the water.

Those are some British scientists. Had you read that complete article?

Dr. PORTERFIELD. No, sir.

Dr. MILLER. It is rather illuminating when you read it. This is just a summary of it.

I think that is all.

The CHAIRMAN. Mr. Abernethy.

Mr. ABERNETHY. No questions.

The CHAIRMAN. Dr. Hedrick.

Dr. HEDRICK. Doctor, since older people drink more water than children and children drink more milk than older people, would not the proper way to give fluorine to children be to have dairies put it in the milk?

Dr. PORTERFIELD. Unfortunately not all of the children drink milk. Water seems to be almost the only universal media of conveying fluorides to children.

I think there was a study out in Colorado some years ago that showed that those children which immediately upon weaning got no more milk but only boiled vegetables and boiled meats showed greater fluorosis than those that had been taking milk. I mention that only to show that there are population groups that do not get milk.

Dr. HEDRICK. Well, I was of the opinion that at least 95 percent of all babies got milk.

Dr. PORTERFIELD. I wish that were so, sir. I do not know whether it is or not.

Mr. ABERNETHY. Will you yield there?

Dr. HEDRICK. Yes.

Mr. ABERNETHY. I do not think that exactly answers the doctor's question. I think Dr. Hedrick has propounded a rather interesting question. It is true, I am sure, that 98 percent of the children consume milk. I realize that occasionally here and there you find a child that does not consume milk.

Dr. Hedrick, would you put your question this way: Would it be advisable, or would that be a reasonable satisfactory method to get fluorine to most of the children by adding it to their milk?

Dr. PORTERFIELD. I do not know whether there are scientific, that is, chemical or physiological reasons, why that would be any different than putting it in the water supply. From the administrative point of view I think there would be this difference: That by having municipal waterworks put it in, where we do have personnel under direct supervision and control—and one of the conditions of our approval is a review of their conditions and continuing control of their activities—we would be better situated than if we attempted to develop the same relationship with the many dairies which are in existence.

Dr. MILLER. Of course, on that point, Doctor, you and I who do not drink milk would not get the fluorine.

Dr. HEDRICK. I am satisfield I do not need any fluorine.

Mr. ABERNETHY. I do not know whether I do or not.

Dr. HEDRICK. I have been fortunate in having good teeth all my life.

The CHAIRMAN. Are you through, Doctor?

Dr. HEDRICK. Yes.

The CHAIRMAN. Mr. Jones?

Mr. JONES. No questions.

The CHAIRMAN. Thank you, sir.

STATEMENT SUBMITTED ON BEHALF OF AMERICAN MEDICAL ASSOCIATION BY GEORGE F. LULL, M. D., SECRETARY AND GENERAL MANAGER, FEBRUARY 27, 1952

The councils on pharmacy and chemistry and foods and nutrition of the American Medical Association made a careful study of all the available data with respect to the ingestion of fluorides in drinking water under natural conditions and when fluorides are added. On the basis of this study, the councils on pharmacy and chemistry and foods and nutrition adopted the following statement, November 2, 1951:

"The council on pharmacy and chemistry and the council on foods and nutrition have been requested to state their opinion regarding the safety of fluoridation of water supplies, a procedure which has now been adopted by more than 140 cities.

"The councils are unaware of any evidence that fluoridation of community water supplies up to a concentration of one part per million would lead to structural changes in the bones or to an increase in the incidence of fractures. The only difficulty so far revealed is a possible increase in mottling of the tooth enamel. The available evidence based on thousands of observations indicates that the incidence of mottling of the enamel in children who drink water containing fluoride up to a concentration of one part in a million is minimal and detectable only by careful dental examination. It occurs only in a small percentage of children and is so slight as not to present a problem from the point of view of appearance or strength of the teeth. Evidence of toxicity other than the effect on enamel has not been reported in communities where the water supply has several times this concentration. After considering the evidence available at this time, the councils believe that the use of drinking water containing up to one part per million of fluoride is safe. However, the use of products which are naturally high in fluoride content, such as bone meal tablets, or of lozenges, dentifrices, or chewing gum, to which fluoride has been added, should be avoided where the drinking water has been fluoridated. In places where children are subject to warm temperatures and consequently drink large amounts of water, a lower concentration of fluoride may be necessary to avoid mottling of the teeth."

The councils purposely refrained from making any recommendation that communities support or oppose projects for the fluoridation of water supplies. It was the opinion of the councils that this question should be answered by the dental profession.

The house of delegates of the American Medical Association at its meeting in Los Angeles, Calif., December 4 to 7, 1951, adopted the following resolution:

"Whereas carefully controlled studies have demonstrated that fluoridation of water supply has been definitely beneficial in the reduction of dental caries in the younger age group; and

"Whereas the council on pharmacy and chemistry has reported that fluoride is nontoxic in community water supplies up to one part per million; and

"Whereas the addition of fluoride to community water supplies seems to have merit; Therefore be it

"*Resolved*, That the house of delegates of the American Medical Association endorse the principle of fluoridation of community water supplies."

The house of delegates of the association went a step further than the councils in endorsing the principle of fluoridation. Again, however, the house of delegates did not urge or recommend that any communities undertake to fluoridate their water supplies.

In summary then, the American Medical Association through its councils on pharmacy and chemistry and foods and nutrition and house of delegates has reached the following conclusion with respect to fluoridation: Fluoridation of public water supplies in a concentration not exceeding one part per million is nontoxic and its principle is endorsed.

Mr. KLEINFELD. The next witness, Mr. Chairman, is here to discuss not fluoridation, but the cosmetic aspects of the committee's investigation.

Will Mr. Crawford take the stand.

The CHAIRMAN. I believe you have been sworn, have you not?

Mr. CRAWFORD. I appeared before this committee about a year and a half ago, Mr. Chairman. I do not recall whether I was sworn or not.

The CHAIRMAN. Will you give your name and address to the reporter, please.

Mr. CRAWFORD. C. W. Crawford, Commissioner, Food and Drug Administration, Washington, D. C.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

TESTIMONY OF C. W. CRAWFORD, COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, FEDERAL SECURITY AGENCY

Mr. KLEINFELD. Mr. Crawford, how long have you been associated with the Food and Drug Administration?

Mr. CRAWFORD. Thirty-five years.

Mr. KLEINFELD. And you are the Commissioner of the Food and Drug Administration?

Mr. CRAWFORD. Yes.

Mr. KLEINFELD. Are you the chief administrative officer of that agency?

Mr. CRAWFORD. That is right.

Mr. KLEINFELD. Please read your statement.

Mr. CRAWFORD. Mr. Chairman and members of the committee, on September 13, 1951, the Food and Drug Administration wrote to the counsel of this committee reporting instances of injury from the use of four classes of cosmetics. In that letter we expressed the view that in the interest of public safety there should be mandatory requirements for adequate pretesting and adequate manufacturing control of new cosmetics before they are placed on the market. Mr. Chairman, with your permission, I would like to submit a copy of that letter for the record.

The CHAIRMAN. Without objection it is so ordered.

(The letter referred to is as follows:)

FEDERAL SECURITY AGENCY,
FOOD AND DRUG ADMINISTRATION,
Washington 25, D. C., September 13, 1951.

Mr. VINCENT A. KLEINFELD,
Counsel, House Select Committee To Investigate Chemicals in Foods,
House Office Building, Washington 25, D. C.

DEAR MR. KLEINFELD: More than 10 years ago there developed in the cosmetic industry a determined effort to produce methods of curling hair which eliminated the elaborate machinery, discomfort, and costly procedures then involved in permanent waves. In San Francisco a company managed by an individual who is primarily an engineer and inventor developed an apparatus fitting on the head and hair which eliminated the heating devices used for permanent waves. The ingenuity and know-how expended in developing the mechanical features of the apparatus were extensive, but the materials and solutions used in connection with it were selected because of their properties for assisting in the curling process without any investigation or study of the possible injurious or toxic effect of such solutions. The heatless permanent wave method thus developed was sold on a franchise basis to beauty salons throughout the United States. The heatless waves were cheaper, less time-consuming, and more pleasant to take.

Shortly after national distribution was effected, a death was reported from Atlanta, Ga., which occurred while the subject was being given a heatless wave in a beauty shop. Tests then made indicated that the solutions were unsafe and likely to cause injury. Thereafter it was necessary to institute over 200 seizure actions to remove the outstanding stocks of the offending wave materials from the market and prevent further injury to the public.

About 8 or 9 years ago the styles in hair arrangement for women resulted in a widespread adoption of what has been facetiously called the washerwoman hair do, which involved piling the hair on top of the head and arranging it neatly so that it would remain in such arrangement for an indefinite period. Among the esthetic draw-backs of this hair arrangement were the stray locks on the back of the neck which did not conform to the arrangement and were left dangling in a more or less untidy effect. To meet the crying need thus created, an immediate popularity developed for some kind of adhesive material which would affix these stray locks in an upward direction and attach them to the remainder of the upswept hair. To fill this need, a Chicago manufacturer created Locks-Up Hair Lacquer Pads. These were in the form of a cotton pad impregnated with a lacquer substance which, when brushed upward around the hair do, increased the tidiness of the arrangement by gluing the hair to the rest of the arrangement. In applying the lacquer pads they necessarily came in contact with the skin and scalp adjacent to the hair.

This development occurred during wartime when there was a scarcity of lacquer materials, shellac, varnish, resins, and glue. Apparently the first product was entirely successful and created an enormous demand. Subsequent batches of manufacture employed unknown and untested adhesive materials, synthetic resins, etc., and the result of that hasty improvising was that hundreds of women throughout the United States suffered significant injury by reason of the poisonous nature of the resins used, which created a contact dermatitis and other painful and disfiguring complications. As a result of regulatory activity of this Administration, the product was eventually removed from the market; but not until a great deal of damage had occurred.

About 4 years ago numerous complaints were received from women whose fingers had been significantly injured as a result of using lacquers marketed in the form of fingernail coatings. Again the ingredients employed were different kinds of newly developed products related to synthetic rubber and no adequate testing was undertaken prior to marketing the coatings to determine whether they might have any propensity for injury. These products are exceedingly complex organic chemicals, more in the nature of mixtures than specific entities, and the only practical approach to evaluating their properties for harm is adequate tests on lower animals or human beings. Because of the complex chemical character of the ingredients, it was very difficult to determine the precise nature of the offending constituents and it became necessary to regard each batch or lot as an entity unto itself and to undertake individual testing. Again, lack of adequate pretesting and experimenting on the public with unknown chemicals resulted in substantial injury to many users of this type of cosmetic. Finally, by belated study and experimentation, manufacturers were able to produce satisfactory articles without deleterious ingredients.

During the month of August 1951, the product of two shampoo manufacturers has been found to contain ingredients which are significantly dangerous when introduced into the human eyes. Both of these products employ polyoxyethylene group surface active agents together with a quaternary compound as the active principles of the so-called dry shampoo. The two manufacturers had acquired wide distribution but had received a considerable number of complaints from customers whose eyes had been injured by inadvertent contact with the shampoo material. Pharmacological tests on animals made by this Administration confirmed the dangerous character of the material when introduced into the eye, and demonstrated that the products have the property of producing an opacity of the cornea which impairs the eyesight for a persistent period of time if not permanently. Accidentally getting shampoo material into the eye is such a common occurrence in the experience of everyone that such occurrence is consistent with the conditions that are customary or usual in shampooing the hair.

After an initial seizure in each instance, these manufacturers agreed voluntarily to remove their products from the market and to attempt to devise suitable substitutes. In either instance had any pretesting whatsoever been conducted by the shampoo manufacturers, notwithstanding the fact that data are generally available which would suggest the extreme likelihood that such ingredients would be dangerous. Again these ingredients, particularly the polyoxyethylene compound, are in the nature of a mixture rather than a chemical entity and the effects of one batch may not be safely forecast from tests made upon another unless the entire group of possible compounds is tested and found innocuous.

These incidents represent some of the high lights of distribution of dangerous cosmetics without adequate pretesting safeguards that have shown up in the last decade. Other less extensive and dramatic instances of similar nature have

occurred. Cosmetics by their very nature are chemical in character or represent a combination of chemicals. New cosmetics are the result of using new chemicals or well-known chemicals in different and new combinations. It seems absolutely essential in the interest of public safety that there be mandatory requirements for adequate pretesting and adequate manufacturing controls of products of this nature. It is abundantly evident that manufacturers generally do not undertake sufficient investigations of the possible injury hazards before placing such products on the market. Many large manufacturers do undertake appropriate tests. For example, the shampoo products of the nature just described were studied by some manufacturers and rejected, after which they were adopted and employed by other manufacturers in reckless ignorance or wanton disregard of the available facts.

The foregoing may be of interest to the members of the select committee of the House as collateral to the subject matter of chemical additives in foods which they are considering.

Sincerely yours,

JOHN L. HARVEY,
Associate Commissioner of Food and Drugs.

Mr. CRAWFORD. In reviewing some of the testimony given before this committee and in reading comment regarding the activities of this committee made by interested parties, we have noted a number of points we think worthy of answer or clarification. The implication we have seen advanced that practically all instances of significant injury from cosmetics in recent years were reported in our letter of September 13 is not true. While cosmetics generally are safe, the cosmetic industry, like every other group, has its fringe of the careless or indifferent or unscrupulous. We have in our files hundreds of complaints from individuals, or physicians and attorneys representing individuals, wherein injury is alleged from the use of cosmetics. We have investigated all the products which were the subject of these complaints. Some were cases of hypersensitivity, where the incidence of unfavorable reaction might be as rare as one in thousands. Others, however, were cases where such reactions occur more frequently—some much more. Still others were cases of primary injury and were not associated with allergies or peculiarities of the individual. We offer copies of a few of these complaints for the record. These are merely examples; our files contain many more.

The CHAIRMAN. What have you in mind?

Mr. CRAWFORD. A few specimen complaints that we have received about cosmetics or alleged injury from cosmetics.

The CHAIRMAN. I think it is advisable at this time that we examine them and reserve decision to give the members of the committee the opportunity to look over them and see if there are any objections.

Mr. CRAWFORD. It is quite agreeable.

The CHAIRMAN. Proceed.

Mr. CRAWFORD. Products complained about include creams containing mercury compounds, depilatories, deodorants, hair straighteners, hair curlers, hair rinses, hair dyes, hair lotions, shampoos, and many other types of cosmetics.

We have been able to take positive regulatory action on harmful deodorants, hair straighteners, and depilatories and other preparations, but in each case such corrective action came after people were injured. Since the burden is on the Government to be able to establish that the cosmetic may be injurious, we must assemble evidence of potential injury before we are in position to institute legal actions. While we are developing the necessary evidence, additional injuries often occur.

We believe that factory inspections of cosmetic manufacturers, which are conducted as part of our routine operations, and the informal comment or advice given by our administrative officers or technical divisions on problems presented by cosmetic manufacturers, have been of real value in restricting the marketing of dangerous new cosmetics. However, with our limited inspection force, which must be used to cover foods, drugs and therapeutic devices as well as cosmetics, it is possible to inspect only a fraction of the cosmetic factories each year.

While most firms are fully cooperative at the time of inspection, many insist on operating in an atmosphere of secrecy. It is manifestly impossible for the Food and Drug Administration with its limited force to determine the composition of the many thousands of cosmetics on the market either by analyses, which are time-consuming even where analytical methods are available, or by observing their manufacture in the plant. It is often necessary to devise new methods before a product can be analyzed. Moreover, many manufacturers can give our inspectors little information about the composition of some of the raw materials used, some of which they purchase under fanciful names and some of which may vary in composition from batch to batch.

It has been said that probably none of the instances of injury outlined in our letter of September 13 would have been prevented had there been a law requiring pretesting before the cosmetics involved were placed on the market. We do not share this view.

In the case of the heatless permanent wave preparation alleged to have been involved in the death of a woman in Atlanta, physicians in attendance said that the preparation caused the death. Although we may have no more actual first-hand knowledge of this case than those who have disputed the conclusions of the attending physicians, we do know that the Food and Drug Administration, following directions and using the apparatus and the solution furnished by a licensee of the company who supplied the Atlanta beauty shop, did produce death in laboratory animals. If any significance can be ascribed to this, and we believe it is significant, it corroborates the physicians' conclusion that the permanent wave solution caused the human death.

If the permanent wave solution had been tested before marketing and had killed laboratory animals as dramatically as it did when we tested it, a legal provision with respect to new cosmetics similar to that on new drugs would undoubtedly have kept the product off the market.

Under any appropriate legislation requiring pretesting, the danger resulting from the change in formula of the lacquer for wayward locks of hair would have been revealed. Any application of the changed lacquer to a reasonable number of test subjects must inevitably have produced some of the reactions which resulted from its widespread use.

In the cast of the fingernail base coatings, or certainly some of them, the exact nature of the ingredients employed never became fully known. Analysis defied the most able chemists. Products of this nature, the composition of which was unknown and analysis of which was impossible, would not have been passed for cosmetic use under a legal requirement that the manufacturer maintain adequate controls to preserve the identity and purity of his product.

In the committee's consideration of this case of injurious nail base coatings, it might be interested in seeing a photograph I have here, a colored photograph, which reveals injury showing a number of the nails that have pulled back for extensive areas from the underlying flesh. [Passing photograph to committee.]

In the case of the shampoos, relatively simple and obvious tests by standardized procedures, such as placing a drop or two in the eyes of laboratory animals and observing results, would have shown the hazardous character of these preparations.

The committee may be interested in looking at some photographs we have of one of these shampoos. It is a colored photograph. The first shows a normal rabbit eye. The second was a photograph of a rabbit eye taken 42 days after installation of two drops of shampoo in the eye. The third photograph shows the same eye 104 days after instillation—corneal opacity and lesions still present. [Passing photographs to committee.]

It has been said that adequate sampling and examination of raw materials which are used in cosmetics would insure safety. Whether the use of the material results in a safe cosmetic depends not only on what the material is but also on how it is treated, processed and worked over, the quantity used, what chemical changes take place, what the final composition and physical properties of the cosmetic are, and how the cosmetics are applied and used. Manufacturers of chemicals usually have no means of regulating the formulas and procedures employed by cosmetic manufacturers who may use their chemicals. We have information that a manufacturer of chemicals refused to supply certain ingredients to cosmetic makers because he knew the cosmetics would be injurious. Nevertheless, a cosmetic manufacturer obtained and used some of the materials by repurchasing from buyers who had obtained them ostensibly for industrial use.

It has been suggested that notification of the Food and Drug Administration 60 days in advance of marketing a new cosmetic would serve to protect the public. Mere notification requires no prior testing. And testing takes time, no matter whether it is done by the manufacturer, the Food and Drug Administration, or anyone else. Such an amendment would be practically valueless in preventing the use of cosmetics of unknown safety, and in protecting consumers from being used as guinea pigs. Such a procedure would compel the Government agency to undertake testing that should be done by the manufacturer who seeks to profit from his idea.

Much has been said about the impossibility of guaranteeing the absolute safety of any substance for all people under all circumstances, and about the toxicity of nearly every substance to hypersensitive individuals. The point is conceded. But this does not mean that nothing should be done toward setting up legal safeguards to minimize other and more avoidable dangers.

By adequate pretesting it can be predicted that a cosmetic will cause injury in a certain percentage of users, or in less than some certain minute percentage. Whenever the pretest injury rate is significantly high, the product should not be put on the market. It is important to recognize that same cosmetic may be sold to millions of people and that even a relatively small percentage of reactions may involve a great many individuals.

Pretesting has been described as quite expensive. This is true in many cases, but not all. But the alternative to the expense of using laboratory animals and human volunteers for testing is to use the public generally as experimental animals, without its knowledge or consent.

There have been inferences that cosmetic injuries are slight and of minor concern only. Actually they have ranged all the way from minor and temporary irritations to fatalities. Fortunately, most of the injuries we have found in recent years have not been serious, although they have caused disfigurement, some permanent but most for only a few days. Even the latter are regarded as of importance by those who suffered the injuries.

Other cosmetic problems under existing law have been discussed before the committee. In section 601 (a) there is a special exemption which permits the marketing of poisonous and deleterious coal-tar hair dyes provided the label cautions the user to make a patch test and warns against use for dyeing the eyelashes and eyebrows. We believe that this exemption should be reexamined. The patch test cannot be accurately interpreted by the layman and is not an effective safeguard against injury. A warning on the label not to use the article as an eyelash or eyebrow dye may serve to prevent blindness or lesser injuries from such obvious misuse, but hair dyes can get into the eyes—especially when applied as a shampoo or lotion. There are a considerable number of hair rinses and color shampoos on the market which are so applied. The chance of getting them in the eyes is the same as for ordinary shampoos and hair lotions.

At the insistence of the Food and Drug Administration, one of these color shampoos has been recalled from the market within the last few weeks. This product was found to be dangerous not only because it contained a particularly dangerous dye, but also because it contained a highly irritating detergent. This color shampoo exhibited a particularly virulent effect upon the eyes of laboratory animals, and human experiences with it have also indicated injury.

We believe the exemption which permits the sale of coal-tar hair dyes, however dangerous, should be modified to restrict the coal-tar colors used to those which are least harmful, and that the warning on the label should include precautions against getting into the eyes.

The question has been raised before this committee as to whether it would be in the public interest to require the listing of ingredients in the labeling of cosmetics. The present law makes no such requirement, although it does require listing of the active ingredients of drugs and of all ingredients in unstandardized foods. We believe the consumer has a right to know also what ingredients are in the cosmetics she uses. And if cosmetics which will occasionally cause a sensitivity reaction are to be allowed on the market, declaration of the ingredients would be of real value to the physician who treats the case, and to the consumer who may avoid further injury by not using cosmetics containing the ingredients to which she has found herself sensitive.

While several improvements might be made in the cosmetic chapter of the law, the most pressing and important problem arises from the absence of any provision comparable to the new drug section requiring adequate pretesting to insure safety of new cosmetics or new ingredients in cosmetics.

When I had the privilege of appearing before your committee on November 28, 1950, I presented the draft of a proposed bill modeled on the new drug section that would require adequate pretesting of new chemical additives in food. A new drug is usually such because it contains some chemical that is not generally recognized by qualified experts as having been adequately tested for safety. As I see it, there is no significant difference in the basic problem arising from the use in drugs of chemicals inadequately tested for safety and that from the use in food or cosmetics of chemicals inadequately tested for safety. The differences seem relatively minor and can be dealt with through changes in draftsmanship.

The new drug section has been highly effective in protecting the public health. Although the drug industry opposed the enactment of that section in 1938, they have since become its enthusiastic supporters. Let me read some quotations from the Odyssey of Modern Drug Research by Robert Burlingham, a book published in 1951 by the Upjohn Co., one of the country's leading drug manufacturers. Please note the similarity between the early apprehensions expressed by the drug industry and those now being expressed by the manufacturing chemists, the cosmetic industry, and some elements in the food industry.

Referring to the new drug section:

> At the time [of enactment] many of the drug manufacturers affected considered the law practically as bad as the medicine that brought it on. The leading pharmaceutical houses did not take quite so lugubrious a view, since they had argued against the bill on the ground that they already had higher standards of quality and safety control than the law would provide. Nevertheless, the entire industry settled down to observing the law and the complex regulations issued under the wide enforcement powers granted to the Food and Drug Administration. And in the course of doing so, the manufacturers—some willy, some nilly—found themselves compelled to increase their scientific and technical personnel, to accumulate a vast body of medical evidence on which to launch their products, and in general to apply the principles of rational therapeutics to all their works. * * *
>
> It is to the credit both of the FDA officials and of the drug manufacturers, who have worked in full cooperation to meet the objectives of the law, that the public has been given needed protection from careless or irresponsible drug making, without any hampering of the free enterprise of drug discovery. On the contrary, as already pointed out, the law gave new impetus to pharmaceutical research and new strength to the ties between drug houses and other medical research facilities outside the industry. Although industry and FDA points of view have often differed and sometimes clashed on administrative matters—which, in this case, are almost entirely matters of opinion—a large majority of the industry would certainly be among the first to recommend a head examination for any manufacturer who wanted to repeal the new drug provisions of the law at this late date. * * *
>
> It is true that most of the big-name, full-line houses—houses like Lilly, Upjohn, Squibb, Abbott, and Parke, Davis, for example—had long maintained rigorous manufacturing controls, high quality standards, large-scale pharmacological and clinical testing of new products, and other standards which the new law compelled the whole industry to adopt. But there is no indication that the law has wrought hardship on any company, large or small, except perhaps for its desirable discouragement of fly-by-nighters who might otherwise have exploited and possibly endangered the public. On the contrary, the law has profited the whole industry to the extent that the public, including the medical profession, now takes for granted the purity and quality of all drugs on the market and their saftey when used in accordance with labeled instruction * * * (pp. 50 and 52).

Mr. Chairman, if the labors of this committee result in the enactment of provisions with respect to foods and cosmetics comparable to the

new drug section, I venture that within a few years you will read similar expressions from the food and cosmetic industries. More important, you will have made a significant contribution to the health and well-being of the American public.

The CHAIRMAN. Dr. Miller?

Dr. MILLER. I think in 1950 I introduced that bill you set up.

Mr. CRAWFORD. That was the Miller bill; yes, sir.

Dr. MILLER. With the things they have said about me since that time, I did not know whether I was right or not. I have had some very critical letters.

You suggested that there might be some amendment to the bill, and you suggested in the draft of it there might be some criticisms. I am not particularly concerned unless the criticisms are valid. On the other hand, I do not feel as if I want to be a party to giving the Food and Drug such dictatorial power over business that it stifles their growth. I do not know whether the bill does that or not, but some of the people thought so and that they would be hit by the bill. Other folks thought some manufacturing cosmetics, those in a bathtub, so to speak, with a few salesmen to go out to sell them are getting by with almost murder, you might say, as to what is in the cosmetics.

I do not know whether you had any thoughts on a revision of the bill. I did not know you were going to be here or I would have had the bill here, the section of it that I thought the wording might be changed to make it a better bill.

I would like to talk with you or your force sometime relative to those suggested changes. In other words, I do not want to stifle new industry. I think they ought to be accountable for what they do.

It seems to me that some of these cosmetics ought to be labeled so people know what is in the cosmetics.

The question of hormones in cosmetics is an interesting thing. I do not think we ought to take the position, "You can't do that, you can't put hormones in," because maybe it would be beneficial cosmetically to some people. If it is, the more power to those people. In other words, the Food and Drug people are not going to take the attitude that here is something, hormones, that should not be prepared and sold to the public.

What is your attitude on the hormones? Can you tell the committee briefly?

Mr. CRAWFORD. Dr. Miller, the underlying principle, it seems to me, on this whole question of inadequately tested chemicals, foods, drugs, and cosmetics is quite parallel. It is just the same.

I have just read you the reaction here that is expressed in this publication of one of the leading drug manufacturers, which, I venture, represents the viewpoint of 95 percent of that industry with respect to this type of control over new drugs. They stress the point that there has been no hampering of legitimate development of the drug industry. I see no reason to fear that a parallel type of control over foods and cosmetics should result in any different end product than what has occurred with respect to drugs.

Dr. MILLER. Doctor, are you familiar with the suit against the American Medical Association by one of the cosmetic manufacturers?

Mr. CRAWFORD. Only in a general sort of way. I knew there was a suit filed.

Dr. MILLER. You were not involved in that?

Mr. CRAWFORD. No; we were not involved in that at all.

Incidentally, you may recall, Dr. Miller, Mr. Chairman, and other members of the committee, that when I presented that draft to the committee I pointed out that it was a draft and that was all, and it was susceptible of improvement. I think probably some revisions of the bill could be made, some provisions could be clarified, Dr. Miller. But as to the fundamental idea, I think the fundamental idea is eminently sound.

Dr. MILLER. I think you are right about that. Especially it is in the public interest, sir.

Mr. CRAWFORD. That is right.

The CHAIRMAN. Dr. Hedrick?

Dr. HEDRICK. Doctor, in your opinion do you think there is any risk in the public using face creams with estrogenic hormones in them?

Mr. CRAWFORD. That have estrogenic hormones in?

Dr. HEDRICK. Yes. Do you think they are detrimental?

Mr. CRAWFORD. We have been suspicious of those face creams from the beginning, but we have never been able to get evidence which we thought would serve as valid court proof of any injury from the use of those face creams in the concentration in which they are used.

Dr. HEDRICK. Why were you suspicious of them?

Mr. CRAWFORD. There had not been enough work done, we thought, to be even reasonably sure that they were safe. There was a statement made in one of the medical journals, I think, which resulted in the suit to which Dr. Miller referred, to the effect they were quite dangerous. But the basis of that assertion was not sustained upon further investigations.

Dr. HEDRICK. In other words, they have never been proven actually harmful to human beings?

Mr. CRAWFORD. That is right. And within recent years there seems to be less and less cause for apprehension because of the wide extent to which the product has been used.

Dr. HEDRICK. That is all.

Dr. MILLER. I would like to ask Mr. Crawford—from the food and drug standpoint, these chemicals, whether in food or cosmetics, is it your attitude that the burden of proof should be upon the individual who is going to introduce the new chemical as to whether it is or is not harmful?

Mr. CRAWFORD. That is right. I think that he should assume the burden of making appropriate investigation which will show beyond any reasonable doubt that what he is going to do will not injure the public health.

Dr. MILLER. Would you have any objections in a new bill to have some limitation of the time which your department might take in determining whether something might or might not be harmful?

Mr. CRAWFORD. I think there is some sort of a limitation, perhaps, in the bill that you have introduced.

Dr. MILLER. I am thinking, of course, of the bread hearings that have dragged out such a long time.

Mr. CRAWFORD. That is an entirely different procedure. Those are public hearings. The hearings held under the new drug section are hearings given to the manufacturer himself and his witnesses and to experts of the Government.

Dr. MILLER. A reasonable period of time for the department to make a decision would be satisfactory to you?

Mr. CRAWFORD. That is right.

The CHAIRMAN. Mr. Jones.

Mr. JONES. On page 2 of your statement here the statement appears:

> It has been said that probably none of the instances of injury outlined in our letter of September 13 would have been prevented had there been a law requiring pretesting before the cosmetics involved were placed on the market.

Who said that?

Mr. CRAWFORD. That statement was quoted in several trade journals as having been given by a Dr. Klamann, a representative of the cosmetic industry, at some convention or meeting in New York City.

Mr. JONES. That is one individual.

Mr. CRAWFORD. It is one individual, yes; and I think that has been endorsed by a good many individuals. But I remember definitely that his statements were quoted widely in the trade press.

Mr. JONES. Now down further on page 3, toward the bottom of the page, you said:

> There have been inferences that cosmetic injuries are slight and of minor concern only. Actually they have ranged all the way from minor and temporary irritations to fatalities.

I note the plural there. I think the only fatality we have had brought to our attention here was on this wave. What other fatalities?

Mr. CRAWFORD. There were fatalities that occurred before the Food, Drug, and Cosmetic Act was enacted, and those fatalities were one of the factors that brought about the inclusion of cosmetics under the present law.

Mr. JONES. What I was interested in is the type of cosmetic that was used which resulted in fatalities. Was it in addition to this hair set or hair wave, whatever it was?

Mr. CRAWFORD. Hair dyes and eyelash dyes and that type of thing.

Mr. JONES. They resulted in death?

Mr. CRAWFORD. Yes; there were a few deaths that we traced down and got authentication of from the use of cosmetics. Poisonous depilatories was another cause of death, I believe.

Mr. JONES. With reference to what you said a minute ago about the burden of proof being on the people who were putting the chemicals in food to show that they were harmless, the thing that has concerned me about that is the long time that the bread hearings and the question of bread softeners has been in the public eye, and during that period apparently the Food and Drug Administration has not been able to prove conclusively that that is harmful, which would lead me to believe that we might be getting into a position of requiring tests that would be unreasonable in that they would be continued over a long period of years before we could conclusively prove to the Food and Drug that a thing was harmless.

Now what comment would you have to make on that?

Mr. CRAWFORD. Well, the bill introduced by Representative Miller requires tests that are reasonably applicable to the article. It does not require the doing of an unreasonable thing. That language is drafted from the New Drug Section, which also requires the application of tests which are reasonably applicable.

Mr. JONES. Well, at the same time, we still have people who contend that the bread softeners are harmful. They cannot prove that, but they are not yet satisfied with the proof of the people who sell it that it is not harmful. So in that case it would be left up to your agency to require proof that it was harmless, would it not?

Mr. CRAWFORD. Reasonably. They should apply every reasonably applicable method to show whether or not it is harmless or harmful.

Mr. JONES. Yes. Is it not a fact, though, there is a fear in the minds of the people who sell those products that if such a law were in effect that the Food and Drug would arbitrarily, or maybe with basis, say that those softeners are harmful and would prevent their sale?

Mr. CRAWFORD. I have never heard the fear expressed exactly in those terms. I have heard them say that Food and Drug would lean over backward and not be satisfied with any reasonable demonstration of harmlessness here. The same sort of thing was expressed with respect to new drugs before the enactment of the provision on new drugs. It has not worked out that way. It is a matter of exercising reasonable judgment.

Mr. JONES. The only thing that brought this up is because these bread hearings have been going on so long and they still have not reached any conclusion satisfactory to a lot of people.

Mr. CRAWFORD. Well, the hearings themselves have been closed for a couple of years, and a tentative order is out now dealing with that whole thing. But it is merely tentative, and it is now in process of being revised upon the basis of exceptions to the order, and a final order is expected to issue very soon.

Mr. JONES. Thank you. No further questions.

The CHAIRMAN. In your statement you suggested that there be informative labeling so that a doctor would immediately know what a product contained in the event that persons should be susceptible to any particular ingredient. From a practical standpoint that would be rather difficult, would it not? Take a lipstick, for example.

Mr. CRAWFORD. I do not believe that would be particularly difficult. You need not require all of this to appear upon the container itself, that is, attached to the immediate container, but it could be given as a circular enclosed within the container, a pamphlet that accompanies the package, something like that.

The CHAIRMAN. Yes; I am just thinking now of the practical aspects of it.

Mr. CRAWFORD. That is right.

The CHAIRMAN. Well, for years the so-called full-line cosmetic manufacturers and those that have specialties have used every laboratory precaution. Some of these fly-by-nights or some of the small manufacturers, let's say, have not had the facilities. I am thinking now of the possibility of freezing them out of business because of unduly heavy restrictions. Do you have any comment to make on that?

Mr. CRAWFORD. Well, undoubtedly it takes finances to conduct adequate testing. The cost of adequate testing may range over a pretty wide spectrum. It may be nominal, it may be heavy, and it may run into thousands of dollars. But it has always seemed to us—and we have had that viewpoint with respect to drugs also—that the person who proposes to exploit a new product of unknown toxicity for application to the human body in the form of a cosmetic or a drug, ought

to make sure, or his responsibility should be to make sure, that he is not going to harm his customers. I do not know of any way in ducking that issue.

The CHAIRMAN. No; I do not from a practical aspect, either.

Mr. CRAWFORD. Some splendid work has been done by the Toilet Goods Association in investigating cosmetic ingredients and making that information available to the entire industry.

The CHAIRMAN. I do not know of anything else.

If there are no other questions, thank you, Doctor. We appreciate your coming here and testifying.

Mr. CRAWFORD. Thank you very much for your courtesy.

Mr. KLEINFELD. Mr. Chairman, I have here a statement by Dr. R. T. Stormont, secretary of the Council on Pharmacy and Chemistry, and secretary of the Committee on Cosmetics, of the American Medical Association, which deals with the cosmetic aspects of the committee's investigation. I suggest that, if the committee wishes, it be made a part of the record.

The CHAIRMAN. Without objection, it is so ordered.

(The statement referred to is as follows:)

STATEMENT OF R. T. STORMONT, M. D., SECRETARY, COUNCIL ON PHARMACY AND CHEMISTRY AND SECRETARY, COMMITTEE ON COSMETICS OF THE AMERICAN MEDICAL ASSOCIATION

We regret the delay in complying with your request for information relative to the work of the committee on cosmetics of the American Medical Association and for recommendations regarding the pretesting of cosmetics which are offered for general sale in this country. It is understood that you are primarily interested in the possible deleterious effects of new cosmetic products.

A general statement describing the history of the committee on cosmetics and its method of procedure, as well as a list of references to injuries attributed to cosmetics, is herewith appended.

There is no doubt but that new cosmetic formulations containing chemicals of unknown hazard or toxicity should be subjected to adequate pretesting procedures to establish safety for use before being released for mass sale to the general public. In addition to determining the effect of the new formulation on the skin, i. e., primary irritant and sensitizing qualities, other tests may be in order. Thus, in the case of a shampoo preparation which is apt to get into the eyes, tests of the effects of a new shampoo formulation on this important structure of the body should be carried out before the product is released for general sale. Reputable firms recognize their responsibility to the general public in this regard and apparently have the necessary tests performed prior to marketing their new cosmetic products.

In an address entitled "Chemicals in Cosmetics" before the section on food, drug, and cosmetic law of the New York State Bar Association on January 23, 1952, Mr. S. L. Mayham, executive vice president of the Toilet Goods Association, Inc., takes the position that dermatologists or physicians, even though individuals of critical judgment, could not possibly predict whether or not a new cosmetic formulation is apt to produce serious injuries. I wish to take issue with Mr. Mayham on that point. Examination of the formula for a new cosmetic may reveal an ingredient which is already known to have a substantial irritant or sensitizing quality or potential toxicity, although the firm which is about to market such a product is unaware of this fact. It is true that if the formula contains chemicals of unknown hazard no one can predict whether or not the consumer is apt to be injured through use of such a product. However, any individual of critical judgment, whether he is a dermatologist, pharmacologist, or layman, can appreciate the need for adequate pretesting of such new cosmetic formulations to insure relative safety for use before they are marketed.

Mr. Mayham's abusive and critical remarks concerning the activities of the American Medical Association in the drug and cosmetic fields are neither warranted nor justified. When the Council on Pharmacy and Chemistry was organized in 1905 there were many elements in the drug industry which criticized or

condemned the purpose and objectives of this council. Gradually, pharmaceutical firms came to recognize the worth-while role and activities of the council in advancing the science of medicine as well as acting for the betterment of the public health, and today the overwhelming majority of ethical drug houses are voluntarily cooperating with this scientific evaluating body to a very high degree. Mr. Mayham intimates that the underlying reason for the acceptance program of the committee on cosmetics is to promote advertising of cosmetic products in AMA publications. This is patently false. There is no charge whatsoever for the seal of acceptance of the committee on cosmetics or that of any of the scientific councils of the AMA. Furthermore, no firm having an accepted product is obligated in any way to purchase advertising space in any of the AMA publications. If the AMA were primarily interested in substantially increasing its advertising revenue, the easiest way of doing this would be to do away with the acceptance programs in spite of the fact that the valuable service which such acceptance programs render to the medical profession and the general public would be lost.

It must be remembered that the acceptance programs of the committee on cosmetics and the scientific councils of the AMA are effective only to the extent that firms participate voluntarily is a system of regulatory control. The AMA does not have the police powers of a regulatory agency over foods, drugs, therapeutic devices and cosmetics, and does not wish to serve in such a capacity. It is my personal opinion that a "new cosmetic" amendment to the Federal Food, Drug, and Cosmetic Act, patterned in a general way after the new drug section, should not present any hardship to the conscientious and reputable manufacturer of cosmetics.

I trust that the foregoing information will be of some value to you and the members of your committee.

GENERAL STATEMENT ON THE COMMITTEE ON COSMETICS

A. History of committee on cosmetics

The board of trustees of the American Medical Association authorized the formation of a joint committee on cosmetics in 1948 primarily to study problems relating to medical interest in cosmetics and also to effect a better understanding of the usefulness of cosmetics. At the first meeting of the committee October 12, 1948, the objectives of the committee were defined as follows: (1) A study and classification of currently widely used cosmetics, (2) a study of the claims made for these various preparations, (3) the determination of the safety or harmfulness of cosmetic preparations, (4) the preparation of a general listing of cosmetics acceptable to the committee and of those it now is unwilling to accept, and (5) the preparation of a series of informative articles for the medical profession and the general population (Hair and Scalp Treatments and Preparations, J. A. M. A., 139: 840–844, March 26, 1949; Hair Dyes, Hygeia, 27: 318, May 1949).

At the second meeting of the committee in January 1948 it was voted that the word "Joint" be dropped from the name of the committee and that it would henceforth be known as the committee on cosmetics. At the same time, a seal of acceptance was adopted to be awarded to those cosmetics which meet the requirements of the committee. Manufacturers were then free to submit their products in conformance with the official rules (a copy enclosed).

During the year that followed over 250 products were submitted for consideration. The majority of these were true cosmetic items as narrowly defined, while a smaller proportion included cleansing agents, baby products, and industrial protective creams. The committee continued to disseminate useful information on cosmetics to the medical profession and the general public through various media available for this purpose. It authorized the publication of the following reports: Lehman, A. J., Health Aspects of Common Chemicals used in Hair Waving Preparations (J. A. M. A., 141: 844, Nov. 19, 1949), and Status Report on Deodorant Soaps (J. A. M. A., 142: 814, Mar. 18, 1950). More than 1,000 inquiries were received from physicians and laymen by the committee office on these subjects.

At present, the committee is continuing its efforts to encourage increased emphasis on necessary manufacturing controls in cosmetic formulation, as well as thorough laboratory and clinical investigation of new cosmetic preparations. The committee also fosters a better understanding of the true usefulness of cosmetics and endeavors to alert the medical profession to health problems which may arise from cosmetic usage. The pamphlet Official Rules of the Committee on

Cosmetics is presently being revised to incorporate changes in patch testing requirements (item 10, p. 4 of official rules). Most recent scientific opinion indicates that a greater number of exposures is necessary to demonstrate sensitizing potentialities. Furthermore, a booklet incorporating the lists of accepted products which have appeared in the Journal (copies enclosed), is being prepared.

The present membership of the committee on cosmetics is as follows:

1. Behrman, Howard T., M. D., assistant clinical professor of dematology, New York University, 2 East Sixty-nine Street, New York, N. Y.
2. Blank, Irvin H., Ph. D., research associate in dermatology. Harvard Medical School, Massachusetts General Hospital, Boston 14, Mass.
3. Foerster, Harry R., M. D., chairman, department of dermatology. University of Wisconsin Medical School, 208 East Wisconsin Avenue, Milwaukee, Wis.
4. Huber, Harry L., M. D., 122 South Michigan Avenue, Chicago 3, Ill.
5. Kehoe, Robert A., M. D., director, Kettering Laboratory of Applied Physiology. University of Cincinnati, College of Medicine, Eden Avenue, Cincinnati 19, Ohio.
6. Lehman, Arnold J., M. D., chief, division of pharmacology, Food and Drug Administration, Federal Security Agency, Washington 25, D. C.
7. Rattner, Herbert, M. D., chairman, department of dermatology at Northwestern School of Medicine, 104 South Michigan Avenue, Chicago, Ill.
8. Rothman, Stephen, M. D., section of dermatology, the University of Chicago, Department of Medicine, Chicago 37, Ill.
9. Zopf, Louis C., M. S., professor of pharmacy, Chief, Department of Drug Service, College of Pharmacy, State University of Iowa, Iowa City, Iowa.
10. Stormont, R. T., M. D., secretary of the council on pharmacy and chemistry and secretary of the committee on cosmetics. American Medical Association, 535 North Dearborn, Chicago, Ill.

B. Method of procedure

All committee business is transacted through a confidential bulletin which is prepared at association headquarters. The Bulletin, which is confidential to the members of the committee on cosmetics, is composed of several sections which are termed editorial pages (yellow pages), the record (which contains discussions and votes), the body (which contains statements, reports, recommendations, etc.) and the vote sheets.

The Bulletin is issued at periodic intervals according to current needs. If the schedule is to be maintained, discussions and votes on proposed actions must be received in the office of the committee on cosmetics within 10 days following the mailing of the Bulletin from the committee's office.

All statements are presented to the committee through the secretary, although the statements may originate from any member of the committee.

The presentation of a cosmetic product is accompanied by a description prepared from the evidence offered by the manufacturer and other available sources, by a report from the referee (who normally would be a member of the committee), a report from the laboratory, and any special committees that might have need to report on the subject. The following Bulletin will present the discussion of the committee members, and the succeeding Bulletin the vote, except when on request of a member the vote shall be postponed for further discussion or the gaining of additional evidence. Postponement, however, shall not be for more than 2 weeks unless specific reasons are set forth with the request.

A majority of the vote cast is necessary for acceptance or rejection of a report or product. If a report and its recommendation is not approved by the majority of the committee members voting, it shall be referred back to the referee for a supplemental report, unless the negative votes are not explained. A supplemental report will be presented to the committee for discussion and will require for adoption a majority of the votes cast.

The chairman may at any time refer the subject to a referee for a new report or to a new referee at the request of the former referee, if such action seems indicated.

A vote mailed late but before the member receives the Bulletin containing the record of the votes cast will be counted and reported in the next Bulletin even if it changes the decision.

When the majority of the votes cast is against the recommendation of the referee, the Secretary may after a lapse of 2 weeks move the opposite action, unless a further report from the referee has been received.

All reports are subject to amendment either before or after the discussion, the amendment being offered for discussion unless this seems unnecessary.

The acceptance of any article may be rescinded by motion, providing a satisfactory explanation for such action accompanies the motion. The motion will be discussed and will require for adoption the majority of the votes cast.

When the committee adopts a report explaining the rejection of an article voluntarily submitted by the distributor or, as occasionally may seem indicated, at the request of the committee, this report will in view of the distributor's cooperation be submitted to him for consideration before publication. If the distributor files no reply to the committee's report of rejection within 21 days from the time the report is mailed, the secretary will release it for publication if the adopted action of the committee also included a recommendation for publication. If the manufacturer or distributor files a reply within the stipulated time, this reply will be referred to the referee for the article, who will report the reply with recommendations to the committee.

While reports from referees or motions require only a majority of the votes cast for adoption, recommendations of the Secretary cannot be adopted if more than one negative vote is cast, unless no explanations are offered with the negative votes.

The committee may initiate an investigation and publish its findings on an article without the article being submitted by the manufacturer or distributor, if such action seems to be in the interest of the medical profession and the public. The findings do not have to be submitted in this instance to the distributor before publication.

Articles that are accepted by the committee will be eligible for advertising with the committee seal as long as the claims offered for the products remain acceptable to the committee. When an article is accepted by the committee, a brief description will be prepared for publication in the Journal of the American Medical Association. At suitable intervals, possibly each year, the accepted articles will be listed with appropriate descriptive monographs in a booklet entitled "Cosmetics Accepted by the Committee on Cosmetics of the American Medical Association."

A meeting of the committee members is usually held annually for the purpose of discussing pertinent problems.

C. Injuries caused by cosmetics

Enclosed is a list of references to articles which have appeared in American Medical Association publications—the Journal and the Archives of Dermatology and Syphilology. These references cover a period from 1940 to date and are believed to be representative of the published papers on adverse reactions to cosmetics. No claim is made that these references are representative of all the types of reactions which may have occurred with the use of cosmetics. Injuries which are not reported in the literature apparently do occur if our inquiry service is an index. We have no knowledge of the legitimacy of these complaints from physicians or their possible incidence since it is not the committee's policy to follow up individual reports involving rare cases of allergy to cosmetics.

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Mr. KLEINFELD. Mr. Chairman, I think the statement of Dr. Dan Dahle, of Briston-Myers Co., referred to by the gentleman in the audience, might well go into the record. I have no objection.

The CHAIRMAN. I want to see what the statement is first.

Mr. KLEINFELD. Perhaps he might show it to you, and perhaps the committee might decide to put it in.

The CHAIRMAN. If you will submit it in writing, I am sure every member of the committee will give consideration to the request. I have no objection. I do not know what it contains. As a matter of fact, I have not objected to a single request for a statement becoming part of the record if it is from a reliable source. We do not want to clutter up the record but we have a right to cross-examine.

Mr. KLEINFELD. Due to the shortness of time, I would personally recommend that it go into the record. I have no objection.

The CHAIRMAN. I would like to see what it is before it does go in.

The committee will recess until Thursday at 10 o'clock.

(Whereupon, at 11:50 A. M., the committee recessed, to reconvene at 10 A. M. on Thursday, March 6, 1952.)

CHEMICALS IN FOODS AND COSMETICS

THURSDAY, MARCH 6, 1952

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE TO INVESTIGATE THE USE
OF CHEMICALS IN FOODS AND COSMETICS,
Washington, D. C.

The select committee met (pursuant to H. Res. 74 and H. Res. 447, 82d Cong., 1st sess., continuing the investigation and study begun under authority of H. Res. 323, 81st Cong., 2d sess.) at 10 o'clock a. m. in room 429, Old House Office Building, Hon. James J. Delaney, chairman, presiding.

Present: Representatives Delaney of New York, Abernethy of Mississippi, Jones of Missouri, and Miller of Nebraska.

Also present: Vincent A. Kleinfeld, chief counsel, and Alvin L. Gottlieb, associate counsel.

The CHAIRMAN. The committee will come to order.

Call the first witness, Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Ast.

The CHAIRMAN. Give your name and address to the reporter.

Dr. AST. I am Dr. David B. Ast. My official capacity here is as representative of the American Public Health Association.

The CHAIRMAN. Just your address, Doctor.

Dr. AST. Director, New York State Department of Health, Albany, N. Y.

(The oath was administered by the chairman.)

The CHAIRMAN. You may proceed.

Mr. KLEINFELD. Mr. Chairman, you will recall that at the end of the last meeting there were three things about which the committee reserved decision as to their inclusion in the record.

The first is a number of complaints of alleged cosmetic injuries which were referred to by Mr. Crawford, the Commissioner of the Food and Drug Administration. I suggest, if the committee concurs, that the letters of complaint be made a part of the record but that the names and products of the companies referred to be omitted in fairness to them. I suggest we put in the letters but delete the names of the companies and the products involved.

The CHAIRMAN. Without objection, it is so ordered.

(The documents referred to are as follows:)

STATE OF WISCONSIN,
DEPARTMENT OF AGRICULTURE,
Madison, September 20, 1949.

Mr. W. A. QUEEN,
Chief Division of State Cooperation, Food and Drug Administration,
Federal Security Agency,
Washington, D. C.

DEAR MR. QUEEN: On September 15, Miss ——— ———, a registered nurse living at * * *, Madison, Wis., and employed at * * * Hospital,

* * * Madison, Wis., reported to this office injury to her right eye suffered from accidentally getting into the eye some of the proprietary deodorant * * *.

Miss ——— stated she had purchased a container of * * * at * * * Drug Store * * * Madison, about 2 weeks ago and when using it on Saturday, September 10, 1949, some of the spray happened to enter her right eye, causing immediate acute pain, redness, and excessive lacrimation, with subsequent swelling. She said she had consulted Dr. ——— ———, * * * Madison, and had received treatment through him at * * * Hospital.

* * * * * * *

I have talked by telephone with Dr. ———, who is much interested in this case and says he places great credence in the history of the occurrence as stated by Miss ———. He found the condition serious enough to warrant hospitalization for a time, but said that by the end of the fifth day the condition was enough better to see there had been real improvement. There had been acute conjunctivitis with necessity of removal of a film which he believed involved the epithelium. We did not go into his treatment in detail, but I believe it included administration of opiates and dilation. At the time I talked with him he said he did not believe the cornea would be permanently damaged.

I also talked with Dr. Arthur L. Tatum, chairman of the department of pharmacology, School of Medicine, the University of Wisconsin, who said that astringents of the nature contained in * * * would coagulate protein sufficiently to give the symptoms suffered by Miss ——— and could result in permanent damage. Dr. ——— said he will be glad to let Dr. Tatum and me know if there is such damage.

* * * * * * *

Very truly yours,

DAIRY DIVISION, FOOD SECTION,
R. R. CROSBY,
Supervisor of Food Inspection.

——— ———,

RICHMOND, VA., *April 8, 1948.*

GENTLEMEN: I would like to bring to your notice a product that I think is dangerous and harmful. I think it would bear analysis or investigation from your department.

The product is called * * * and I am enclosing the leaflet that accompanies each tube sold. You will notice in the directions for use that the manufacturers say "allow it to remain on 5 to 10 minutes, depending upon the texture of your skin." I myself used the cream, but after it had been applied for only 1 minute I experienced such great burning and irritation of the skin that I had to remove the cream. I have spent a week trying to subdue the irritation and redness of skin as a result of using this hair remover. As a service to future buyers I think the product should be investigated.

I would be interested to hear from you.

Yours truly,

Mrs. ——— ———.

P. S.—I bought the cream in a * * * store and used it for underarm hair. The leaflet does not forbid use of the cream for this purpose, and I used it in good faith accordingly.

[Letter undated; received March 9, 1951]

DEAR SIR: I would like to know if you have inspected and passed the * * * product as harmless.

A friend used the product on my hair Thursday, and my scalp and forehead is still a mass, mess, too) of sore scabs from the product. Is it possible there is an acid formation present during the hair-dyeing treatment? The pain caused from the solution and the sores resulting from it give me this conclusion. Just try it out and see for yourself. To top it off, it didn't even change the color of my hair.

Thank you.

Mrs. ——— ———.

WASHINGTON, D. C.

DECEMBER 27, 1949.

Re: * * *.

PURE FOOD AND DRUG ADMINISTRATION,
Washington, D. C.

GENTLEMEN: * * * has been putting out "a delightful cream that beautifies." It is packaged in the normal beauty-cream jar with a label telling its advantages. In very small print on the bottom line it discloses that it contains 3 percent ammoniated mercury and 2 percent powdered calomel.

On December 23 my 10-year-old daughter used some of the cream to beautify her little self and was severely burned all over the face. It took nearly 24 hours for her face to come back to normal, and she had to spend the entire day in bed.

I wish to inquire as follows:

1. Does not a total of 5 percent mercuric compounds come within the classification of poison?
2. Would that concentration be poisonous to an infant (internal)?
3. Is it possible that long continued external use over months or years might result in cumulative mercuric poisoning?

I believe that adequate labeling could give considerable protection. My daughter has stated that she would not have dared to use it if it had borne the normal poison label. If it were properly labeled, mothers would realize the danger and would not leave it within range of infants.

* * * * * * *

Very truly yours,

——— ———.

DETROIT DERMATOLOGICAL SOCIETY,
Detroit, Mich., November 9, 1951.

ERWIN E. NELSON, M. D.,
Food and Drug Administration,
Federal Security Agency, Washington, D. C.

DEAR ERWIN: We in the Detroit area are somewhat concerned about * * *, which is registered by the United States Patent Office. Of course, as with so many preparations, we see individuals who are allergic to them, and I think rightly this warning should be attached. However, it is surprising how many persons simply neglect to do a patch test. Our chief concern, however, and I discussed this with several eye men, is about this statement that "this product should not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness." Certainly there is a possibility, in the ordinary use of the preparation on the scalp, that inadvertently some of the shampoo may get into the eyes. We in the local dermatological society feel, and I know it is also the feeling of some ophthalmologists, such a product should not be on the market.

* * * * * * *

Sincerely yours,

HARTHER L. KEIM, M. D.

[Letter undated; envelope postmarked November 23, 1948]

BAY CITY, MICH.

FEDERAL BUREAU OF FOOD AND DRUGS,
Detroit, Mich.

DEAR SIRS: I bought * * * deodorant made by the * * * at the * * * Drug Store, Bay City, and it poisoned me. Under both arms I broke out bright red, and it swelled up, and it is so painful and itchy that I cannot work or even walk without holding my arms up. I've missed 4 weeks' work already. It is just beginning to peel now.

What can I do about this? I've used deodorants and body powders all my life, since I'm old enough, and I've never had a break-out or any trouble of any kind before.

I would appreciate a prompt reply, and thank you.

Mrs. ——— ———.

Mr. KLEINFELD. You will also recall that you had reserved decision on an address by the executive vice president of the Toilet Goods Association entitled, "Chemicals in Cosmetics." I think the members now feel that, too, should be made a part of the record.

The CHAIRMAN. What is his name?

Mr. KLEINFELD. S. L. Mayham, executive vice president of the Toilet Goods Association. It is an address before the section on food, drug, and cosmetic law, New York State Bar Association, January 23, 1952.

The CHAIRMAN. Let that be part of the record.

Dr. MILLER. Yes, I think it should be. I have read Mr. Mayham's address. Of course, we must realize he was addressing a group of men in a public meeting. There are some very excellent suggestions in the letter.

I would lean over backwards, Mr. Chairman, to have it put in the record although it is critical.

The CHAIRMAN. Without objection, it is so ordered.

(The statement referred to is as follows:)

CHEMICALS IN COSMETICS

Address by S. L. Mayham, executive vice president, the Toilet Goods Association, Inc., before the section on food, drug, and cosmetic law, New York State Bar Association, January 23, 1952

There are three phenomena of American life which would seem to have a direct bearing on the present agitation for further control of raw materials designed for use in the manufacture of cosmetics and toilet preparations.

The first of these is the tendency, whenever some minor ill appears in our economic or social system, to quickly pass a law about it and then to forget the whole matter. This has led to many ill-advised pieces of legislation, and I sometimes think that at least once a year Congress should spend a month or two doing nothing but repealing laws which have become antiquated and which were too hastily designed to ever have worked in the first place.

The second is the tendency of bureaucrats, even such nice bureaucrats as those making up the personnel of the Food and Drug Administration, consistently to seek additional authority and more law for their bureaus to enforce. In the present case this tendency is the more remarkable because, on many occasions, officials of the Food and Drug Administration have said, both publicly and privately, that they are seriously handicapped in the enforcement of the present Food, Drug, and Cosmetic Act by shortage of money, and by shortage of personnel in both the laboratory and the field. So here we have them asking for more law when from their own mouths they admit they are unable adequately to enforce the law which they already have.

The third phenomenon always happens every 2 years when the entire membership of the House of Representatives comes up for reelection. It consists of individual Congressmen seeking issues on which they believe they can be returned to Washington for another 2-year term. What they look for is a popular, but poorly understood, situation in which they can view with great alarm the dangers facing their constituents, and where they will never be called upon to explain the actual nature of these perils either to their constituents or to anyone else. Witness the Massachusetts State bill No. 1054 which would bar a well-known deodorant from sale in that Commonwealth.

When you add to these three the success story of Mr. Rudolph Halley, which must indeed be a spur to counsel for any legislative investigating committee, you have in my opinion the real background behind the investigation of the use of chemicals in cosmetics.

This agitation and this investigation should not lead to the introduction or the passage of additional legislation. The provisions of the present law, as they affect cosmetics, are entirely adequate to control any situation which is controllable with any type of law whatever. Of course, the present law will not catch the deliberate crook nor will the present law catch the manufacturer who is consistently and deliberately careless in his manufacturing and testing pro-

cedures. No law which conceivably could be passed by Congress would catch these deliberate violators.

The coal tar color provisions of the present act, for example, represent about as severe a law on this subject as could be conceived. They require that every batch of coal tar color to be used in cosmetics be individually tested and approved by the Government which assigns a batch number to appear in all transactions involving the color until it is actually consumed. Severe penalties are provided for violations.

In spite of this, over the period of years since the law was put into effect, out of 95 cases of adulteration, 23 arose from the use of noncertified or uncertified colors.

What is required under the present law, and I say this with the greatest respect for the Food and Drug Administration which I consider to have done an outstanding job of law enforcement, is better enforcement and a somewhat changed direction in enforcement activities. The Food and Drug Administration has consistently ignored the definition of cosmetics contained in section 201 (i) (2) of the act. This provision states, "The term cosmetic means * * * (2) articles intended for use as components of any such articles * * *." In other words, the law defines as a cosmetic any chemical or other article intended for use as a component of cosmetics or toilet preparations.

A survey of the adjudicated cases indicates that this provision has been invoked in ouly two cases since the law was passed. One of these was to correct a coal tar dye situation where another remedy would probably have worked equally well.

Chemicals, and especially new chemicals, to be used as ingredients in cosmetics, are not produced by small and irresponsible companies. They are almost without exception manufactured and sponsored by great chemical houses which for years have specialized in the production of things difficult to make by the smaller companies. They are manufactured by companies with names such as Eastman Kodak, du Pont, Atlas Powder, Dow, Monsanto, and others. I think it would be no exaggeration to say that, despite the responsibility and knowledge of these companies, few of them realize that the products which they offer to the cosmetic manufacturers are, in fact, cosmetics as soon as they offer them for that purpose. I know of no case in which the Food and Drug Administration has ever brought this to the attention of a chemical manufacturer.

These companies are not in the business of producing things which will harm the ultimate consumer, when used as they suggest they may be used. They are in a position to undertake elaborate series of tests, not only to determine the suitability of the product for the purpose for which it is offered, but to determine that no possible harm can come to the ultimate consumer through the use of these products. This is what I mean by a better direction to enforcement. Let us utilize section 201 (i) for a change and see if it does not exercise a salutary influence on the whole situation.

So much for the possibility of changed enforcement. Let us now consider just how necessary additional legislation is. In this connection I have surveyed the 189 (and there are only 189) adjudicated cases on cosmetics since the enactment of the law in 1938. During those 13 years there have been 95 adjudicated cases brought under the adulteration provisions of the act. One of these was won by the defendant, leaving 94 such cases. Of these 94 cases, only 59 were brought because of the presence of harmful or deleterious ingredients used in the manufacture of the cosmetics. The other 35 were because of the presence of filth, products being held under insanitary conditions, and for other reasons technically and legalistically classified as adulterations. Of these 59 which were brought because of the presence of a harmful ingredient, 22 came in the very early stages. There was a new law and cosmetics had never been previously controlled. These 22 were brought for the correction of conditions made illegal by a law which, previous to its passage, had not been illegal. In other words, this was to correct bad history and once it was corrected the law was supposed to keep the situation under control.

Hence, we have only 37 cases of the presence of harmful ingredients adjudicated after the very early stages of law enforcement. Of these, three were hair dyes on which the caution label was unsatisfactory. They were brought under section 601 as containing a harmful ingredient and therefore would have to be included. However, ignoring them because of their peculiar nature, we now have a total of 34 adjudicated cases due to chemicals in cosmetics; 14 of these involved a permanent waving fluid of almost uniform composition, 10

others were hair lacquers, again of almost uniform composition. You might almost treat these 24 cases, because they involved substantially the same products, as merely two cases, and if you did you have a bare dozen cases other than these. But let us be generous and say there were 34 cases where the presence of a chemical in a cosmetic was brought to court and proved to have done a harm.

This was over the period of 13 years since the law went into effect. During that time, the Toilet Goods Association has estimated that the total sales of cosmetics amounted to $8,860,000,000. Being most conservative with respect to an estimated price, per unit, this would amount to sales over the 13 years of 26,301,000,000 packages of cosmetics sold and consumed in the United States. I contend that to find only 34 cases where harm has arisen from the presence of a poisonous ingredient in over 26 billion packages of cosmetics sold is not only "de minimis" but is really "much ado about nothing."

Since there is nothing to correct, I hesitate to take the time to outline the corrective steps which the course of the Delaney committee hearings to date would indicate are in the minds of the committee and others seeking new legislation. However, the remedies which would seem to be in their minds are of such character that I think they should be examined, in case, by some mischance, legislation on this subject should ever be introduced. Several types of remedies would appear to be in the minds of those who would like to see additional law.

The first is to write into the cosmetic section of the present law something akin to the new drug application provision of the present law, section 505. In my opinion, this type of remedy, which is apparently foremost in the minds of the officials of the Food and Drug Administration, would be ill-advised for two principal reasons. One of these is that the processing of a new cosmetic application by the present staff of the Food and Drug Administration would involve very heavy new duties for some members of the staff, placing an almost intolerable burden upon their limited facilities. It would require spreading very thin all the necessary research work involved in a new drug application, in cases where such an application is really necessary.

Let us see how this proposal would have dealt with the "horrible examples" cited by Mr. Harvey of the Food and Drug Administration in his solicited letter to the Delaney committee. The first of Mr. Harvey's "horrible examples" had to do with a new permanent-waving preparation alleged to have killed a woman in Atlanta, Ga. Medical testimony on this particular case, however, is very conflicting and the manufacturer whose product was alleged to have caused this fatality has what seems to be adequate medical testimony to the effect that the woman was not killed by the solution at all but died from quite other and natural causes. In any event, no suit for damages was ever brought against the manufacturer; no other fatality or serious damage was caused from the preparation which has long since disappeared from the market, not because of this but because of the fact that it became outdated. This case, I think, may be deleted from our consideration.

The second of these "horrible examples" were hair lacquer pads designed to keep the hair in place at the time of the popular upsweep hairdo. There is no doubt in the world that the original lacquer pads, designed for this purpose just prior to the war, would have passed a new cosmetic application had such a provision existed in the law at that time. What happened was that after the original lacquer pads had been used for some time and without any damage, wartime shortages caused the supplier of these lacquers to make certain changes in his formulation, without notice to his cosmetic-manufacturing customers, and then the damage took place. A new cosmetic application would not have changed the picture and the procedure of seizure and recall which was followed in this case would have had to be followed in any event. This might have been followed by revocation of the approval of the new cosmetic application, but this would have come later, because action of this kind by the Food and Drug Administration does not customarily happen until after the damage has taken place. Incidentally, a number of new drug applications accepted and passed by the Food and Drug Administration have later been revoked under similar circumstances.

The third "horrible example" cited by Mr. Harvey was a nail base coat which caused certain alleged damage to susceptible individuals. In this case, one of the manufacturers who placed these base coats on the market did enough research so that they would have passed a new cosmetic application had one been in existence. They were tested on several hundred individuals without damage. Subsequently again, a change in formulation by the supplier brought about damage, but no new cosmetic application would have prevented this from happening. Incidentally, it was pointed out to the Food and Drug Administration at the

time when this unfortunate accident occurred, that all these nail base coats originated from one important supplier. The Food and Drug Administration never cited or never made a seizure of the product of this particular house, nor, so far as I have been able to find out, did they ever consult with this house with a view to stopping the damage. Rather, they engaged in difficult, expensive and almost futile efforts to pin the damage on the cosmetic manufacturers. I submit that this is not the course best designed to protect the public although it may be the method best designed to build a reputation for the bureaucracy. Incidentally, the Food and Drug Administration using all of its fine technical facilities never has found out what actually caused this allergic reaction.

My second reason has to do entirely with the character of the cosmetic industry. The cosmetic industry is made up of approximately 1,800 Companies. Under the definition of "small business" recently issued by Secretary of Commerce Sawyer, more than three-quarters of these companies are definitely small-business enterprises. A study of the research and development work needed to prepare a new drug application would lead to the belief that somewhere in the vicinity of $12,000 to $20,000 must be expended by a manufacturer in preparing the application, this amount being for chemical, biological, and clinical experimentation of a character required to convince the Administration of the harmlessness of such a drug.

Let me cite one or two examples of how this might affect an industry built up of very small units such as is the cosmetic industry. Twenty years ago three brothers and a brother-in-law started in the cosmetic business, placing on the market a product on which certainly a new cosmetic application would have been required had there been this provision in the law. Their capital was approximately $600, most of it borrowed. Today that company enjoys a world-wide business in excess of $25,000,000 annually. Its fine products are available at reasonable prices to men and women all over the United States. It has been a peculiarly American success story.

About 8 years ago, again two brothers with very limited resources started to manufacture a cosmetic product on which again a new cosmetic application would have had to be filed. Six years after they started the business they sold it for a reported $20 million. Again I submit that this is a peculiarly American success story.

Neither one of these companies would or could have been started had this proposed remedy been a part of existing law at the time when they were organized. Among the 1,200 little fellows now engaged in the cosmetic industry and those that are coming in from time to time, who knows how many Revlons and Tonis may develop, not only to their own profit but to the great benefit of consumers throughout the United States and as a badly needed example of how the American system of free enterprise works.

From my observation of the industry, I would say that more than two-thirds of the present cosmetic manufacturers do not have sufficient resources to file one single new cosmetic application should there be such a provision in the law. Do the proponents of this remedy desire to put two-thirds of the industry, represented by these small, responsible, hard-working manufacturers out of business or in a position where they cannot progress and thereby turn over a larger share to the well-financed larger units? I think they do not. I think they merely have not thought the remedy through.

The second proposal—and this seems to have originated in the mind of counsel to the Delaney committee—is to list all ingredients of every cosmetic on the label. Obviously it must have originated with someone who knew very little about the cosmetic business or about cosmetics in general. Even under the very severe drug provisions of the law, the drug manufacturer has to list only his active ingredients on his label. He is not required to list the vehicles nor the flavor, nor even the coloring.

Let us look at this proposal for a moment and consider how it would work. First, I have examined a very great many cosmetic formulas. Few of them contain less than 15 ingredients and many of them contain 50 or more. Just where on the label or in the labeling would this list appear in distinguishable form? If you consider the perfume ingredients used in some of these products, you might well have to list 150 items on the label. The names of most of these would be completely unfamiliar to anyone who might want to read them, and again, I cannot imagine a label large enough to contain this information. Just what effect would the listing of these ingredients on the label have had on the three "horrible examples" cited by Mr. Harvey? I suggest substantially no effect at all. It would not have prevented, minimized or controlled these three unfortunate accidents.

In committee hearings to date it seems that the background for this most curious proposal is that some people suffer cosmetic allergies just as some people suffer food allergies, drug allergies and in fact allergies to almost everything except air and water. These unfortunate people, it is supposed, would like to have the names of all ingredients in a cosmetic listed so they can avoid those to which they are allergic. Also, it is pointed out that in the nonstandardized foods, ingredients are listed on the label. With this latter statement in mind, I undertook to ask 100 women a simple question relative to food labels. The question was this "Does the label of the food product which you buy at the grocery store contain the names of the ingredients?". Out of 100, 90 did not know and frankly confessed that they did not know. Out of the 10 who knew, 6 reported, in response to further questioning, that they never read the ingredients named although they knew they were listed. The other four sometimes read them and not a single one said she always read them.

But let us go back now for a moment to the lady who is allergic. She goes to a dermatologist who discovers that she is allergic possibly to lanolin, so she wants to avoid lanolin in cosmetics. If her dermatologist really knows his business he is aware of the fact that there are already a number of cosmetic manufacturers making hypo-allergenic cosmetics which exclude every possible known allergen and that these companies are willing to make up on special order at very, very reasonable prices cosmetics, excluding the ingredients to which the individual may be allergic. So, the industry itself has made provision to take care of these cases of allergy and it would seem quite folly to insist on listing all the ingredients of a cosmetic, when absolutely nothing in the way of public protection would be accomplished by doing it.

The third proposal which has arisen before the Delaney committee is a little more subtle and by its very subtlety it discloses its origin. The suggestion is made, in questioning a witness, that his products should be submitted to the American Medical Association for approval or, at least he is asked if he does submit them to the committee on cosmetics of the American Medical Association for approval. Further questioning brings out the desire of someone to have a law creating a committee, consisting largely of dermatologists, to control cosmetics.

I think we do not have to examine that proposal at length to know where it originated. I have watched the American Medical Association's activities in the drug field for a period of over 30 years. I have seen the strangle hold which this group has upon the manufacturers of medicines and drugs, and at the same time, I have witnessed the growth of what might almost be called a "medical publication trust" with as fantastic a record of earnings as any publishing house that I know of, and I was for many years in the publishing business.

This proposal suffers from three great difficulties. First, if it went through, it would require another expensive Government bureau, and a bureau which could not possibly do either the public or the industry any good whatever. Dermatologists are accustomed to treating diseased conditions of the skin. They are not in general equipped to consider the application of cosmetics or other products to the healthy skin and, with the exception of a few outstanding dermatologists who have made a study of cosmetics and of the cosmetic industry, their ignorance of cosmetics is fantastic. If there were to be a committee of this kind, and it would still be inconceivable to have one, dermatologists and in fact medical men should play a very small part in it. Rather, we should have pharmacologists whose entire training has been along the lines of determining the properties of materials and whether they possess any harmful or deleterious qualities.

Just what effect would this proposal have had upon the "horrible examples" cited by Mr. Harvey? I suggest that a committee of dermatologists could have done nothing in any of these cases until after the damage had been done and very little then. They could not even have known that any damage was likely to be done until long after it had happened. There would have been no cure here for these unfortunate accidents.

A few years ago, the AMA organized its committee on cosmetics. It appointed a number of doctors as members of the committee. Not one of these, so far as a search of their previous records and experience is concerned, had any specialized knowledge of the cosmetic industry at all. In announcing the formation of the committee, the AMA indicated that it was for the education of the medical profession into the usefulness of cosmetic products. Many people were probably taken in by that announcement. The educational results, after three or more years of operation, have been two articles consisting of a rehash of well-known facts and fables about cosmetics which have appeared in the AMA Journal and the an-

nouncement that the committee would, in the future, issue a seal of acceptance—(note I say "acceptance" and not "approval")—to manufacturers who would submit their cosmetics to the committee along with a considerable amount of verbiage regarding their constituents, claims, etc.

If the AMA issues a seal of acceptance for advertising (and it carefully avoids saying "seal of approval") obviously the seal means acceptance of advertising. What it really says is, "we are accepting your advertising in our already very profitable journals and we hope you will do a great deal of it, and then you will get a nice little seal which the public may, and probably will, misinterpret as meaning that we have approved your product, which of course we do not and we cannot, since we know very little about it." Just how gullible can we be and should we pass a law endorsing and enforcing such a questionable activity?

These are the three remedies which have been proposed or appear to have been proposed at the hearings. If there are others, they have not come out into the open and again I submit that to cure no disease at all, the dosage of these remedies is enough medicine to kill the patient three times over.

Finally, may I point out what the real remedy to this situation is, if indeed it needs any remedy at all. I would call attention to the record of the hearings of the Delaney committee to date. Practically every industry witness who has appeared has shown how carefully he insists upon control of the product from the time of purchase of the raw material until the ultimate consumer actually uses it. He tests the raw materials, he tests the products in process, he tests the finished product and he does so without any great love for the public but because he knows that if a manufacturer puts out something that is harmful and poisonous he will not stay in business. It is strictly a selfish proposition.

Automobile manufacturers do not put out automobiles with defective wheels. You need no law to compel them to put good wheels on their cars. Neither do cosmetic manufacturers put out poisonous lipsticks nor use poisonous ingredients knowingly in their product.

Nearly 13 years ago the Toilet Goods Association began the study of cosmetic raw materials with a view to establishing standards for these materials which would insure their complete safety and their adequacy for the purpose. During that time, near 40 such material standards have been issued by the Toilet Goods Association. In the case of many of these standards the limits of the Toilet Goods Association specifications are more severe than those in the United States Pharmacopoeia or the National Formulary. This is a continuing work and it will be continued until virtually the entire list of cosmetic raw materials has been covered by Toilet Goods Association standards.

During that period we have succeeded, for example, in tremendously improving the quality of titanium dioxide by eliminating harmful impurities from supplies offered to the cosmetic industry. We have done the same thing in a product more frequently used in medicine, zinc oxide. The present law permits the Food and Drug Administration to improve standards for products intended for use in drugs. During the same period, I recall no case in which a Food and Drug Administration standard has superseded one in either the USP or NF. It remained for the toilet goods industry to do that.

Three years ago the Toilet Goods Association established a substantial grant at the laboratory of applied physiology at Yale University. This grant was to study cases of allergy, sensitivity and irritation arising from cosmetics and from a list of nearly 2,000 ingredients used from time to time in cosmetics. This is a costly venture. It will be without profit to anyone except the medical profession, which will learn more from the published work of this study than it has been able to learn from any source in the past regarding this highly difficult branch of medicine. During the same period the only work sponsored to any great extent by the AMA has been the raising of a fund of millions to fight legislation which they believe detrimental to their interests. I think, gentlemen, the contrast between the work of the industry as shown by the activities of the Toilet Goods Association with those of the Federal Security Agency and of the AMA is too clear to require further elaboration.

There is nothing wrong with the use of chemicals in cosmetics. The cases which have been brought out in the record of the Delaney committee and produced by the staff of the Food and Drug Administration are not nearly so numerous or not nearly so dangerous to the public health as those which occur every day in the food field and in the drug field. The fringe operator and the crook you cannot catch by any law and the present law, if properly enforced, is completely adequate for the purpose of public protection for which it was originally intended. The industry is consistently improving its methods, improving its

raw materials and its finished products. It intends to continue to do so, but it does not want to see the present law ruined by the attachment of amendments which will not only not work but which will prove damaging, if not disastrous, to the large number of small manufacturers from whose ranks will come the giants of the future, and from whose further study of cosmetic problems will come new and better cosmetics and toilet preparations to the benefit of the health, well-being and morale of American men and women.

Mr. KLEINFELD. Last is the one referred to by some gentleman at the last hearing, which is a statement by Dr. Dan Dahle, director of production research of the Bristol-Myers Co. Since the gentleman felt so strongly about having it in the record, I think it might be well to make it a part of the record also.

The CHAIRMAN. Did the members receive a copy?

Mr. KLEINFELD. Yes.

The CHAIRMAN. I have no objection.

Mr. KLEINFELD. Congressman Jones and Congressman Abernethy indicated no objections to it. It indicates the opinion of this gentleman that no further legislation is needed in the cosmetic field.

The CHAIRMAN. Do you recommend it go in?

Mr. KLEINFELD. I do.

The CHAIRMAN. Without objection it is so ordered.

(The statement referred to is as follows:)

STATEMENT BY DAN DAHLE

QUALIFICATIONS

Education: Ch. E. 1919, Chalmers Institute of Technology, Gothenburg, Sweden; M. S. 1934, American University, Washington, D. C.; Ph. D. 1936, American University, Washington, D. C.

Experience: 1919–1920, Teaching high school, Sweden; 1920–1921, chemist, Advex Manufacturing Co., Brooklyn, N. Y.; 1921–1923, chief chemist, Wilckes-Martin-Wilckes Co., Camden, N. J.; 1924–1928 assistant State chemist, Tallahasse, Fla.; 1928–1932, chief chemist, United States Food and Drug Administration, Savannah, Ga.; 1932–1938, research chemist, United States Food and Drug Administration, Washington, D. C.; 1939–1943, acting chief, Cosmetic Division, Food and Drug Administration, Washington, D. C.; (I do not recall the exact date here, but there was no change of duties involved when I was made full Chief); 1942, on loan to War Production Board as consultant on cosmetics; 1943–46, Chief, Cosmetic Division, Food and Drug Administration, Washington, D. C.; 1946 to present, director of research, Bristol-Myers Co., Hillside, N. J.

While working in the Cosmetic Division, Food and Drug Administration, I was responsible for the writing of the specifications for the certified coal-tar colors listed in S. R. A. F. D. C. No. 3 and for the development of analytical methods for the examination of cosmetics and coal-tar colors.

STATEMENT

The Bristol-Myers Co. manufactures the following cosmetics and toilet preparations:

Ammens medicated powder
Benex brushless shave
Ingram improved cream
Ingram lather shave
Ipana tooth paste
Ipana penicillin tooth powder (really an Rx drug item)
Mum deodorant
Mum lotion deodorant
Trushay hand lotion
Vitalis hair tonic
Vitalis hair cream

In these products we use 48 raw materials, listed below
(The list referred to is in the files of the committee.)

The tests made by us on materials and finished products may be divided into two categories; manufacturing standards and special tests.

Manufacturing standards are set up to cover all our plant and laboratory operations and consist of the following:

1. Raw material specifications, covering as far as possible, all raw material characteristics, sufficiently variable to have an effect on safety, quality, or uniformity of our products. No raw material is accepted for use that does not conform to specifications, unless special permission is granted by the research department.

2. Formulas, stating the amounts and percentages of ingredients in the various products.

3. Process standards, covering the essentials of the actual manufacturing operations, and consisting of:

(*a*) Flow chart: A diagram showing the movement of materials through the process.

(*b*) Material standards: A statement of the required characteristics of all materials, raw or otherwise, brought into the department for processing. Wherever applicable U. S. P., N. F. or T. G. A. specifications are used.

(*c*) Operating standards: A tabulation of temperatures, pressures, and other variables to be adhered to.

(*d*) Operating instructions: Detailed directions for carrying out the process.

(*e*) Sample instructions: A statement of the method of sampling, sample marking, frequency of sampling, and tests to be made on each sample.

(*f*) Finished product standards or limits within which processed material may be passed for shipment or further processing.

4. Analytical methods constituting standard procedures for use in the analytical laboratory in testing raw materials as well as intermediary and finished products.

Manufacturing standards must be adhered to in all details. No deviation is permitted unless it is authorized in writing by the plant manager and/or the director of research.

All incoming batches of raw materials are tested by our control department. The manufacturing department is not permitted to use any material until such material has been released by control. The control department also examines various samples taken during the processing as well as the finished product, first prior to filling and second prior to shipment.

In addition to manufacturing standards we maintain a plant inspection. The purpose of this inspection is to supplement the "analytical control" by a system of "plant control" in which technically trained, impartial inspectors are constantly checking manufacturing, finishing, and shipping conditions which may affect the quality of our products.

The inspectors immediately report all deviations from standards or other unfavorable observations to the department head. If the inspector believes that the condition is serious enough to warrant shutting down the process or operation, he has the authority to do so before notifying the department head.

The inspectors are instructed to pay particular attention to quality of the product at every stage of inspection and to make daily reports of all observations and recommendations to the head of the control department.

They also visit the shipping department at least once a week for a routine check on storage conditions (such as goods standing in sunlight, in areas which are hot, cold, or exposed to the weather, etc.) Insofar as said storage conditions may affect product quality.

The research department furthermore makes a periodical check of formulas and processes.

In such an audit of a process, every detail of the standards is checked, from the formulas to finished-product standards and including such raw-material specifications as are concerned. (If any portion of the standards cannot be checked at the time of the audit, the operator or his superior must be questioned as to what is the usual procedure.)

All raw materials are checked as to condition and marking of containers, suitability of storage conditions, conformity to raw-material specifications, and as to whether all shipments have been analyzed and passed before use.

Under sample instructions, a check is made to see that samples are taken, marked, and analyzed as specified.

All recording and indicating instruments are checked for accuracy and adjustments made or replacements arranged for when necessary.

Special tests are made during various stages of the development of a new product or the substitution of a new raw material for one already in use. These tests include chemical as well as pharmaceutical and clinical experimentation. Briefly our stages of product development are—

(1) Literature search by an experienced librarian on any material the properties of which are not sufficiently known to us. Particular emphasis is laid on collection of all available data concerning toxicity (acute and chronic), irritation, and sensitization.

(2) Contact with reputable suppliers of the material in question for their available data on (*a*) composition, (*b*) chemical properties, (*c*) toxicity, irritation, sensitization, (*d*) application properties, (*e*) specifications and tolerances, and (*f*) price.

(3) Pharmacological testing of raw material where indicated.

(4) Preparation of experimental formulation series.

(5) Stability testing of experimental products under various conditions.

(6) Testing the finished product by actual use on a limited number of humans. (This is preceded by pharmacological testing on animals and often clinical testing on humans if there is any reason to suspect that the product may be toxic, irritating, or sensitizing.)

(7) Consumer panel testing (i. e., comparison under actual use conditions by 500 to 600 persons of the new product with an existing product, designed for a similar purpose).

(8) Sales test in a limited area.

If the product passes these tests successfully it is considered ready for general distribution.

So much for the testing done by our control and research departments. As to the question of need for further strengthening the Food, Drug, and Cosmetic Act of 1938, I frankly feel that additional enforcement under the present provisions of the act would serve the same purpose and should be tried first.

DAN DAHLE,
Director of Production Research,
Bristol-Myers Co.

The CHAIRMAN. Mr. Kleinfeld, will you proceed, please.

TESTIMONY OF DAVID B. AST, D. D. S., M. P. H., ALBANY, N. Y., REPRESENTING THE AMERICAN PUBLIC HEALTH ASSOCIATION

Mr. KLEINFELD. Dr. Ast, what degrees do you hold?

Dr. AST. I hold a degree in dentistry, D. D. S., from New York University, 1924; master in public health from the University of Michigan in 1942.

Mr. KLEINFELD. Generally speaking, what has been your professional background since you received your degrees?

Dr. AST. I was in the practice of dentistry from 1924 to 1938. During that period I was a member of the teaching staff at New York University. I was a member of the hospital staffs of Presbyterian Hospital and Fordham Hospital in New York City. I was a contributor to a textbook on periodontia, edited by Dr. Samuel Charles Miller.

In 1938 I assumed my role as director of the dental services for the New York State Department of Health and have been so employed continuously from that time.

During this period I have had appointment as special lecturer in public health administration at the School of Public Health, Columbia University, and at the Albany Medical College.

Mr. KLEINFELD. Your statement represents the viewpoint of the American Public Health Association?

Dr. AST. It does.

Mr. KLEINFELD. What is your specific connection with the Newburgh experimental study?

Dr. AST. I initiated the Newburgh-Kingston caries fluorines study in 1944 and have directed it continuously since then.

Mr. KLEINFELD. Please read your statement.

Dr. AST. Prior to 1944 several epidemiological studies determined:

1. A number of potable water supplies in different parts of the United States naturally contained fluorine in varying concentrations from 0.05 parts per million to more than 10 parts per million.

2. When the fluorine concentration was in excess of 1.0 part per million, mottling of the enamel of the teeth of some of those ingesting such water during the years of tooth development resulted.

3. The degree of mottling, that is, very mild, mild, moderate, or severe, and the extent in terms of numbers involved were directly proportionate to the concentration of fluorine in the potable water consumed during the years of tooth development.

4. No deleterious effects were reported from the ingestion of waterborne fluorides other than mottled enamel.

5. Where the fluorine content was approximately 1.0 part per million, children ingesting such water during the years of tooth development had—

(*a*) Sixty percent less dental caries experience in their permanent teeth than comparable aged children in fluoride-free areas.

(*b*) There were six times as many children completely caries-free as compared with those in flouride-free areas.

(*c*) Seven-five percent less first permanent molar loss than in comparable aged children in fluoride-free areas.

(*d*) All of these benefits without any disfiguring mottled enamel.

In June 1944, the New York State Department of Health initiated a study to determine whether the supplementation of the fluoride ion in communal water supplies having less than the optimum—approximately 1.0 part per million fluorine—would have the same beneficial effects as noted in areas where this concentration was found naturally in the potable water. Studies were subsequently initiated in Grand Rapids, Mich.; Brantford, Ontario; Sheboygan, Wis.; Evanston, Ill., and other areas.

The Commissioner of Health for New York State appointed an advisory committee to assist the State Department of Health in planning the various types of tests which would be necessary to determine the efficacy and safety of such a program. This committee consisted of:

Dr. Katherine Bain, director, Division of Research in Child Development, Children's Bureau, Washington, D. C.

Dr. John Caffey, roentgenologist, the Babies Hospital, Columbia Presbyterian Medical Center and professor of clinical pediatrics, College of Physicians and Surgeons, Columbia University.

Dr. William J. Gies, professor of biological chemistry, College of Physicians and Surgeons, Columbia University.

Dr. Harold C. Hodge, professor of pharmacology, University of Rochester, Rochester, N. Y.

Dr. Philip Jay, assistant professor of oral pathology, University of Michigan, Ann Arbor, Mich.

Dr. Samuel Z. Levine, pediatrician in chief, New York Hospital, New York City.

Dr. Maurice Pomeranz, attending roentgenologist, Hospital for Joint Diseases, New York City.

This committee, with two changes, has been functioning continuously from 1944 through the present period. The two changes were: Drs. Jay and Pomeranz have been replaced by Dr. Basil G. Bibby, director of the Eastman Dental Dispensary, Rochester, N. Y., and Dr. John W. Fertig, Professor of biostatistics, School of Public Health, Columbia University.

Two comparable cities, Newburgh and Kingston, N. Y., each with a population of approximately 30,000 were selected for the study and control areas respectively. The potable water in each city had from 0.05 to 0.1 parts per million fluorine naturally.

The study was planned on a 10-year basis because it was presumed that any potential dental benefits which may accrue would be the results of the effects of ingested water-borne fluorides on the developing and calcifying teeth. The crowns of the permanent teeth are all, with the exception of the third molars, calcified by about age 8 so that it would take about 10 years to study the full benefits of such a program.

The types of examination which were agreed upon were:

1. Dental examinations for all of the elementary school-age children in both cities, about 3,200 children in each city.

2. Medical examination, including complete physical examinations, X-ray study of the hands, forearms and legs, and blood and urinalyses.

These medical examinations were initially made for a group of 500 children in each city with an age distribution of 100 under age 1, 100 age 1, 200 age 2 to 5, and 100 age 5 to 9. During each of the first 3 years of the study an additional group of infants under 1 year of age was enrolled.

In addition to the above examinations special opthalmological and otological examinations were made for smaller groups of children annually.

All of the above types of examinations, both medical and dental, were first made in Newburgh in 1944 to 1945 to obtain a base line prior to fluoridation of Newburgh's water supply, and in 1945 to 1946 in Kingston for the base-line data. The dental examinations have been made on an annual basis in each city thereafter and the medical examinations during the early years of the study were made two and three times a year. They are now made annually.

At the last medical examinations made in 1950 to 1951 there were 613 children in Newburgh and 482 children in Kingston, age a little over 1 to 15 years in the study. For the dental examinations 2,905 children in Kingston, and 3,344 in Newburgh age 4 to 14.

All of the X-ray films, of which several thousand are taken each year, are read by Dr. John Caffey, a member of the advisory committee and the author of a leading textbook—Pediatric X-Ray Diagnosis.

The data for the medical examinations for 7 years in Newburgh and 6 years in Kingston show no differences in the findings among the children studied in Newburgh and Kingston.

It is considered that the earliest sign of chronic fluoride toxicity would be manifested in the teeth and in the bones, and especially in the bones during the years of most rapid growth and development. A large number of children have been studied who have had fluoridated water from birth to early childhood and whose mothers drank fluoridated water during the prenatal period.

X-ray study of the hands, forearms, and legs of these children reveal no differences in the children in Newburgh and Kingston, maturation is neither accelerated nor retarded.

Blood counts and hemoglobin determinations as well as urinalyses reveal no differences in the study and control groups.

I would like to add here that the fluorine content excreted in the Newburgh children studied is of the same order as is found in McClure's work in areas of natural fluoride waters.

The clinical examination which is made by a board qualified pediatrician consists of a complete physical examination with special attention to the skin, nails, and thyroid gland. These examinations reveal no differences in the children in the two cities.

With reference to the effects of ingested water-borne fluorides on adolescents and young adults we note McClure's work in studying fluoride excretion, and height, weight, and bone-fracture experience among high-school boys and young adult males coming from natural fluoride areas and fluoride-free areas.

In regard to urinary excretion of fluorine, McClure states:

> An efficient urinary elimination of fluorine appears to be characteristic of individuals residing in certain fluoride areas of the United States where the drinking water contains 0.5 to 5.0 parts per million fluoride. The metabolism of fluorine under these conditions seems to be a normal function of the human body and seems characterized by a condition approaching metabolic equilibrium, at least in the adult organism.

With regard to height, weight, and bone fracture experience he reported no differences among those studied in comparable fluoride and fluoride-free areas.

The analysis of the dental examinations shows a continuing downward trend in dental caries experience in the permanent and deciduous teeth of the children in Newburgh, as compared with those in Kingston.

And I would like to refer you to the mimeographed chart which I think you gentlemen have, which illustrates the downward trend in Newburgh as compared with the original study in 1944–45, and its relationship to the dental caries experience in Aurora, Ill., where they have naturally 1.2 parts per million of fluorine in the water supply.

You will note that after 5 years of fluoride experience in Newburgh the children through age 8 have a better or equal DFM rate as is found in Aurora, and that the rate for the older-aged children is rapidly approaching the Aurora date.

Among the 6- to 12-year-old children examined at the outset of the study the Newburgh children—and I refer you now to table I—had a 2 percent higher dental caries experience rate for permanent teeth as compared with Kingston. After 5 years of fluoride experience——

Dr. MILLER. How do you account for that—that the Newburgh children had a 2 percent higher dental caries than those in Kingston before you started your experiment?

Dr. AST I don't think that 2 percent is significant, but I am certain that——

Dr. MILLER. But you mention it. It must be because you mention it.

Dr. AST. I mention it merely to relate the next sentence to it.

I should say for the record that I do not consider the 2 percent difference of any great significance. We do not find the same DMF rate in all areas.

Dr. MILLER. What caused the 2 percent difference in your opinion? It is there.

Dr. AST. I have no idea. I would not venture a guess.

Dr. MILLER. You do not think it means anything then?

Dr. AST. No; I do not think it is significant at all. I would consider the initial Newburgh and Kingston data comparable.

Among the 6- to 12-year-old children examined at the outset of the study the Newburgh children had a 2 percent higher dental caries experience rate for their permanent teeth as compared with Kingston. After 5 years of fluoride experience the Newburgh rate was 40 percent lower than that in Kingston.

In regard to the decidous teeth the Newburgh children age 5 to 8 had 5 percent more dental caries experience than the same aged children in Kingston. However after 5 years of fluoride experience the Newburgh rate was 35 percent lower than that in Kingston. And that data is on table II.

A further analysis of the potential protective action of ingested fluoridated water at approximately 1.0 part per million fluorine was made to determine the number of 5- and 6-year-old children who had been reared on Newburgh's fluoridated water from birth or early infancy. Since at ages 5 and 6 the deciduous central and lateral incisors begin to be exfoliated naturally, it was arbitrarily determined that children with all of their deciduous cuspids, first and second deciduous molars present and caries-free were considered completed caries-free. This is a reasonable assumption to make, because one does not usually find caries in the central and lateral incisors without finding it also in the molars, since the molars are the most susceptible teeth to caries.

In the initial examination, Newburgh had 17 percent fewer children aged 5 and 6 with all of their deciduous cuspids, first and second deciduous molars completely caries-free than did Kingston. In the 1950–51 examinations, after 5 years of fluoride experience Newburgh had 64 percent more such caries-free children than did Kingston. And that data is found on table III.

In November 1950, the American Public Health Association after extended consideration by its committee on research and standards adopted the following resolution:

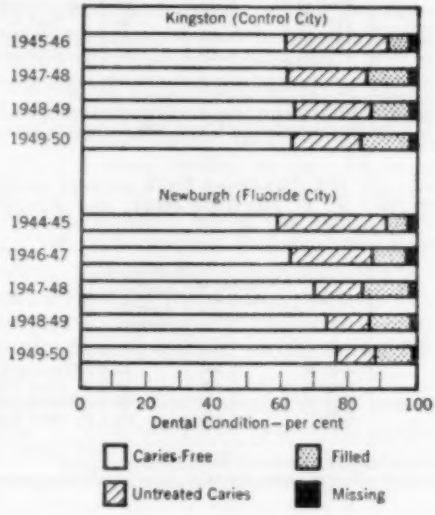
> Whereas accumulated evidence indicates a sound basis for the fluoridation of public water supplies for the partial control of dental caries: Therefore be it
> *Resolved*, That this procedure be recommended as a safe and effective method for reducing the prevalence of dental caries.

In January 1951 the commissioner of health for New York State brought to the attention of the New York State Public Health Council, the data from the Newburgh-Kingston study and the corroborating evidence from studies elsewhere in the country. While the Newburgh-Kingston study was not yet completed—and I might add is continuing and will continue for the minimum of 10 years—the evidence was so encouraging that the public health council approved a statement of policy to the effect that the fluoridation of public water supplies is recommended subject to the provision of adequate control measures in accordance with the specified requirements of the State commissioner of health and in accordance with the sanitary code.

In all probability, the testimony before this committee has already been made concerning recommendation for water fluoridation by official and nonofficial health agencies and national health organizations in the United States. The unanimity with which the many agencies and organizations concerned with the health of the people of this

country have recommended water fluoridation as a safe and effective public-health procedure to control dental caries should serve as strong evidence that the facts have been adequately reviewed. I know of no public-health procedure which has had the extensive and comprehensive study on human populations that water fluoridation had before it was recommended as a satisfactory public-health procedure.

(The tables submitted by Dr. Ast are as follows:)



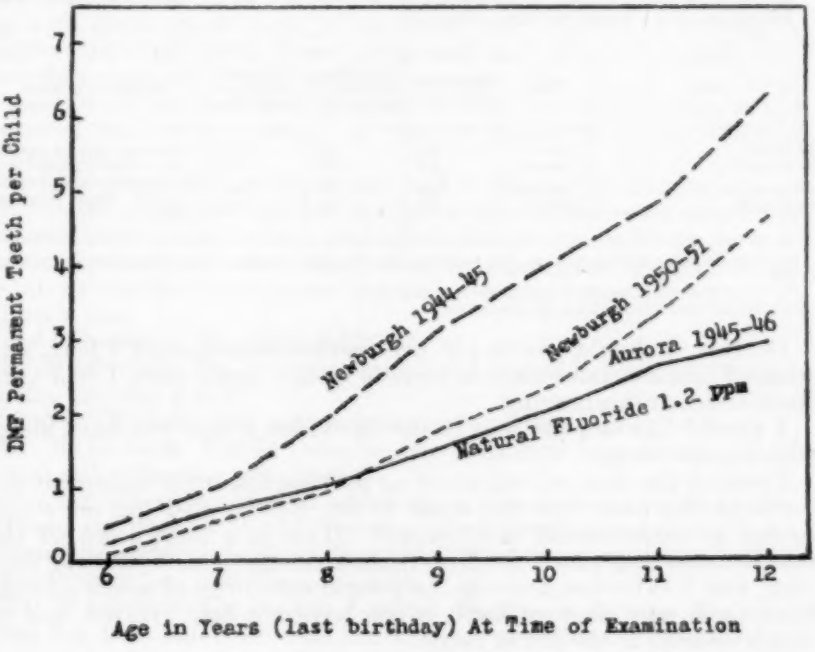


TABLE I.—*Age adjusted [1] DMF [2] rates per 100 erupted permanent teeth of children age 6 to 12, inclusive, in Newburgh, [3] N. Y. (fluoride city), and Kingston, N. Y. (control city), 1944–51*

City	Year	Number of children examined	DMF per 100 erupted permanent teeth	Relative difference
Kingston	1945–46	2,553	20.2	Newburgh rate 2 percent higher than Kingston rate.
Newburgh	1944–45	2,810	20.6	
Kingston	1950–51	2,410	21.7	Newburgh rate 40 percent lower than Kingston rate.
Newburgh	1950–51	2,709	13.0	

[1] Age adjusted to the permanent tooth population in Kingston in 1945–46.
[2] DMF includes teeth decayed, missing (lost subsequent to eruption) or filled.
[3] Sodium fluoride added to water supply beginning May 2, 1945, to increase concentration to 1.2 parts per million.

TABLE II.—*Def [1] rates per 100 deciduous teeth present in children age 5 to 8, inclusive, in Newburgh, [2] N. Y. (fluoride city), and Kingston, N. Y. (control city), 1944–51*

City	Year	Number of children examined	Def [1] per 100 deciduous teeth present	Relative difference
Kingston	1945–46	1,345	35.3	Newburgh 5 percent higher def rate than Kingston rate.
Newburgh	1944–45	1,426	37.0	
Kingston	1950–51	1,414	30.8	Newburgh 35 percent lower def rate than Kingston rate.
Newburgh	1950–51	1,643	20.1	

[1] Def includes deciduous teeth decayed, indicated for extraction or filled.
[2] Sodium fluoride added to water supply beginning May 2, 1945, to increase concentration to 1.2 parts per million.

TABLE III.—*Children with caries free deciduous cuspids, first and second molars, in children ages 5 and 6, inclusive, in Newburgh, [1] N. Y. (fluoride city), and Kingston, N. Y. (control city), 1944–51*

City	Year	Number of children [2]	Number, children [3] caries free	Percent, children [2] caries free	Relative difference
Kingston	1945–46	602	132	21.9	Newburgh rate 17 percent lower than Kingston rate.
Newburgh	1944–45	677	123	18.2	
Kingston	1950–51	524	157	30.0	Newburgh rate 64 percent higher than Kingston rate.
Newburgh	1950–51	730	359	49.2	

[1] Sodium fluoride added to water supply beginning May 2, 1945, to increase concentration to 1.2 parts per million.
[2] Children with all 12 specified teeth present.
[3] Children with all 12 specified teeth caries free.

Dr. AST. I should like to add one further statement, if I may, and which I did not have time to include in my paper since I had very short notice of this hearing.

I should like to refer you to the bar chart which you have along with my statement.

I regard the data on this chart as perhaps the most important observation we have thus far made in the Newburgh-Kingston study so far as dental caries is concerned. This is a breakdown of the dental caries experience for first molars among 6- to 9-year-old children, and it is broken down in the several categories of missing teeth, filled teeth, and decayed teeth which have not been treated, and to which we refer as the unmet needs.

You will note that in Kingston the missing tooth factor, which is represented by a black bar, remains about the same throughout the several years of study, whereas in Newburgh that missing tooth factor has been reduced by approximately 60 percent.

The dotted area—if we compare year for year we will note that the number of teeth filled in each city is about the same, which would indicate that the amount of dental care available in each city is comparable. However, the unmet needs, which is the crosshatched bar, remain about the same in Kingston, whereas in Newburgh that factor of unmet needs is being very radically reduced.

Now the importance of this observation is this: We understand from our epidemiological studies that even if our fondest expectations are realized from water fluoridation we could expect to find only about a 60 percent reduction in new dental caries. If, however, this downward trend should continue, we may reach a point where with our present complement of dentists, using the techniques with which we are familiar today, we will reach a point where dental caries can be controlled. We then, will not have any significant factor of unmet needs, and with our privately practicing dentists taking care of such caries as will occur, we will probably reduce this missing tooth factor to an absolute minimum, and we will not be faced with the accumulation of unmet needs.

Now this accumulation of unmet needs is far more serious than appears on this chart. I should like to refer you to the findings of the Selective Service after the examination of the first 2 million men in 1941. The Army regulations at that time indicated that in order to be eligible for military service our young men had to have three sound anterior teeth in the upper jaw occluding with three sound teeth in the lower jaw and three sound posterior teeth in the upper jaw occluding with three sound teeth in the lower jaw. So out of a possible complement of 32 teeth, if our young men had 12 teeth in good position, they were eligible for military service. Yet, almost 10 percent of our young men had to be rejected at that time because they could not meet those requirements. It was the prime cause for rejection at that time.

In fact, it got so bad the Army had to change its regulations in order to get an Army together, and after that it indicated that those with remedial dental defects could be inducted into military service. Then, of course, we were faced with this tremendous program of dental corrections in the armed services.

Thank you.

The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Ast, what compound is used in Newburgh to get fluorine into the water?

Dr. AST. We are using sodium fluoride, 95 percent pure.

Mr. KLEINFELD. Would there be any difference in your opinion if sodium silico-fluoride were used?

Dr. AST. Based on studies which have already been made by Dr. McClure the Public Health Service, the fluoride ion derived from sodium silico-fluoride will produce the same caries prophylactic effect as the fluoride ion in sodium fluoride.

Mr. KLEINFELD. The reason I asked, Doctor, is because the committee has been informed that the District of Columbia, which is to

fluoridate its water in the near future, is going to use sodium silicofluoride.

Doctor, you are here to represent the American Public Health Association?

Dr. AST. That is right.

Mr. KLEINFELD. I have here a copy of the American Journal of Public Health and the Nation's Health. That is published monthly by that association?

Dr. AST. Correct.

Mr. KLEINFELD. The issue I have is that of January 1952, volume 42, No. 1.

On page 44 there is an article entitled "Choice of Fluoridating Agents in Control of Dental Caries."

Are you familar with that article?

Dr. AST. Yes, I am, sir.

Mr. KLEINFELD. It is written by C. L. Howell, D. D. S.; L. E. Burney, M. D., M. P. H., F. A. P. H. A.; Harry G. Day, Sc. D.; and Joseph C. Muhler, D. D. S., apparently, respectively, assistant director, division of dental health, Indiana State Board of Health, Indianapolis; State health commissioner, Indiana State Board of Health, Indianapolis; chairman, department of chemistry, Indiana University, Bloomington; and assistant professor, department of chemistry, Indiana University, Bloomington, Ind.

Are these persons qualified persons, in your opinion?

Dr. AST. Indeed, in their respective fields.

Mr. KLEINFELD. I want to read you a few sentences of this article and ask for your opinion.

On page 44 the following statements are made and I quote:

> The dental caries experience (DMF) of Grand Rapids, Mich., children aged 5, 6 and 7, is practically identical with that of a comparable group at Aurora, Ill., where the natural fluoride content is 1.2 parts per million. There is every reason to expect that each year, upon reexamination, the succeeding age group of Grand Rapids will also compare favorably with that of Aurora.

Do you agree with that, sir.

Dr. AST. I do, sir.

Mr. KLEINFELD. So that, as I understand this statement, it is reasonable to believe that based upon what we have learned from Aurora, Ill., where the natural fluoride content is 1.2 parts per million of fluorine, we will get the same reduction of dental caries by artifically fluoridating water; is that correct?

Dr. AST. Comparable; yes.

Mr. KLEINFELD. I see. Then similarly, is it natural to expect that we will get the same amounts, degrees, and percentages of mottling?

Dr. AST. Possibly. Yes; I would agree.

Mr. KLEINFELD. On page 45 of the same article, Doctor, the following statement is made, and I quote:

> Several communities have added other fluoride compounds to their public water supplies. The most commonly used is sodium silico-fluoride (fluosilicate). The reason for using other fluorine compounds is that some are less expensive, while others are easier to handle and administer than sodium fluoride. Many justify these considerations on the ground that all fluoride compounds behave similarly in dilute solutions. Since the fluoride compounds are to be added at a level to furnish approximately 1 part per million fluorine, it has been supposed that all compounds would be completely ionized, yielding fluoride ions as the only form of fluorine. If this were true and if the only other consideration

were cost, then any source of fluorine could be used if it yielded the desired concentration of fluorine in solution.

Are you in accord with those statements, Dr. Ast?

Dr. AST. No. No; I am not in accord with those statements, because we already have adequate evidence, as demonstrated by the United States Public Health Service, that certain compounds will yield a fluoride ion which will do what sodium fluoride, what the fluoride ion from sodium fluoride will do in rat experiments. And most of our early work, our laboratory work in our caries, fluorine relationships were done with animal experimentation.

McClure has demonstrated that the fluoride ion in sodium silicofluoride will produce the same caries prophylactic effect as the fluoride ion from sodium fluoride. He also demonstrated that the fluoride ion from potassium flurophosphate (KPF_6) and sodium fluoracetate (CF_3COONa) seem to be unavailable to the experimental animals when given by mouth or injection.

Mr. KLEINFELD. Well, then, you disagree with these gentlemen?

Dr. AST. I disagree with some of the things they state.

Mr. KLEINFELD. Yes.

Dr. AST. And I would like to also add, if I may, that while that paper appears in the official organ of the American Public Health Association, as is common with the journals of most organizations, the association does not assume the responsibility for the opinion expressed by the authors of the papers so published.

Mr. KLEINFELD. I see.

Doctor, in the same article on page 46, the following statements are also made, and I quote:

However, McClure commented on this subject by stating: "As additional data are obtained, particularly with reference to dental caries effects, conclusions may be warranted regarding the possibility of substituting sodium fluosilicate for sodium fluoride as a water-fluoridating agent. The data accumulated thus far, however, do not justify any commitments in this regard."

Then the article continues:

Even though the evidence were available indicating caries reduction similar to that obtained with sodium fluoride, the results would not be indicative of what effect sodium silicofluoride might have in reducing caries in a developing tooth. In addition to this, Muhler, Nebergall, and Day have shown that some compounds reduce the incidence of decay in rats much more than sodium fluoride, yet the amount of fluorine deposited in the femurs is only one-third to one-half as much. It appears, then, that other criteria besides the amount of fluorine available by analysis should be considered when evaluating new fluoride compounds.

What is your opinion of those statements, Doctor?

Dr. AST. Well, I think those statements are correct, but I should like to indicate that this article which is published in, I think it was January of 1952, is that right, the date of that Journal?

Mr. KLEINFELD. Yes, sir.

Dr. AST. In January of 1952, but was submitted for publication some time before then. And McClure's work on the effectiveness of the fluoride ion from sodium siloco-fluoride was published in the Public Health Reports, and I think the date of that is November 23, 1951, following a publication which he had done on the determination of the availability of the fluoride ion from several compounds containing fluorine.

Mr. KLEINFELD. Would you say that there is apparently some difference of opinion between these gentlemen and Dr. McClure and yourself?

Dr. AST. I would.

Mr. KLEINFELD. Again this article continues as follows:

> Most of the more recent articles emphasize the fact that sodium fluoride and sodium fluosilicate can be used interchangably so far as the engineering aspects are concerned, giving no mention of the caries-reducing ability of the different compounds. The very obvious consideration of all these studies is whether or not compounds other than sodium fluoride will satisfactorily reduce human dental decay. If the only consideration in choosing a compound were its ability to furnish fluoride ions, then so far as the reagents suitable for use in public water supplies are concerned, almost any fluoride compound would probably suffice. This is implied in McClure's data. Using the fluoride compounds topically, this rationale is not correct, for when various fluorides are highly concentrated, as they must be for use in conventional topical procedures, the ionization of the different salts is variable and certainly it is not complete. Thus, equivalents of fluoride ions may not be available.

What is your opinion on that, Doctor?

Dr. AST. I think that we have not completed all of our studies on the use of fluorine, nor do we expect that we will ever be through with all of the fine details of studies.

McClure is still continuing his work, and he is continuing the study of fluorides in various compounds.

We have to use the information which we have available and proceed if we are to make progress.

Again I refer you to Public Health Reports, November 23, 1951, volume 66, No. 47, in which McClure demonstrates in his animal experimentation the caries reduction and fluorine retention in bones and teeth of white rats as he works with the several fluoride compounds. And he demonstrates in this paper that the fluoride ion in sodium fluoride and the fluoride ion in sodium silico-fluoride act the same way.

Now that does not indicate that the fluoride ion from any fluoride compound will act that way. Where new compounds are suggested, of course, they will have to be studied. But if we are referring now to a comparison of sodium fluoride and sodium silico-fluoride, I think the evidence is quite clear that the effectiveness, so far as its caries prophylactic effect is concerned for sodium silico-fluoride and sodium fluoride, is very good.

Mr. KLEINFELD. Again, there seems to be some difference of opinion on that, Doctor.

Dr. AST. Yes. I might also add in this article to which you refer, these authors have not done any animal or human experimentation on which to base their opinions. This is all laboratory work, test-tube work.

Mr. KLEINFELD. And what animal experimentation has the other group done?

Dr. AST. Well, McClure has done his rat studies.

Mr. KLEINFELD. On reduction of incidence of dental decay?

Dr. AST. That is right.

Mr. KLEINFELD. You do believe, however, Doctor, that you know of no public health procedure which has had the extensive and comprehensive study on human populations that water fluoridation had before it was recommended as a satisfactory public health procedure?

Dr. AST. Yes.

Mr. KLEINFELD. On page 47 of this same article, Doctor, the following appears:

Neither the hamster nor the rat experiment was intended to answer the question of the relative effectiveness of various fluoride compounds when fed during periods of tooth development.

By the way, this last quotation was specified in the article as having appeared in the May 1951 issue of Nutrition Reviews. Again, quoting:

If the pathways for utilization of the fluoride ion are reasonably similar at the two different stages of tooth life, there is a real possibility that the availability of the ion from different compounds may also influence materially the effectiveness of these compounds when administered during tooth development. These experimental data should be considered by public health administrators and by groups of dental practitioners responsible for the selection of the fluoride compound to be used for the treatment of communal water supplies. On the basis of present knowledge, it would seem that use of any compound other than sodium fluoride for this purpose should be considered experimental until demonstration of the availability of the fluorine in that compound has been made in satisfactory human experiments.

I gather, too, Doctor, you disagree with the statements?

Dr. AST. In part.

Mr. KLEINFELD. Dr. Ast, I have here a publication entitled, "Science," volume 115, No. 2982, February 22, 1952, a publication of the American Association for the Advancement of Science.

Are you familiar with that publication, sir?

Dr. AST. Yes, I am. I am not familiar with that particular issue, but I am familiar with the publication.

Mr. KLEINFELD. Is it a reputable publication?

Dr. AST. Yes, it is.

Mr. KLEINFELD. There is an article here entitled, "The Fluoride Content of Placental Tissue as Related to the Fluoride Content of Drinking Water," by Dwight E. Gardner, Frank A. Smith, Harold C. Hodge, D. E. Overton, and Reuben Feltman; connected with School of Medicine and Dentistry, University of Rochester, Rochester, N. Y.; New York State Department of Health, and Division of Dental Research; Passaic General Hospital, Passaic, N. J.

Are you familiar with the reputations of these gentlemen?

Dr. AST. Yes.

Mr. KLEINFELD. What are their reputations?

Dr. AST. Very good.

Mr. KLEINFELD. And what is placental tissue?

Dr. AST. Placental tissue is that tissue taken from the placenta which is the tissue by which the unborn child is attached in the pregnant mother.

Mr. KLEINFELD. I would like to read you parts of this article, Doctor, and ask you for your opinion, and I quote:

Current programs to fluoridate water supplies as a dental caries control measure have stimulated interest in the extent to which the fluoride might be retained by the various tissues of the body. Considerable evidence is available to show that much of the fluoride is excreted in the urine, but there is little information on the possible accumulation or storage of the fluoride not excreted.

Do you agree that there is little information on the possible accumulation or storage of the fluoride not excreted?

Dr. AST. There is so little that is not excreted, I wonder whether it is a factor at all. But I would go along and say that we have not yet completely studied the storage of fluorine in cases where it is stored.

Mr. KLEINFELD. Is not that a rather important consideration, Doctor?

Dr. AST. No; I don't think so.

Mr. KLEINFELD. I will continue quoting:

A previous study of normal human blood fluoride concentrations of residents of Rochester and Newburgh, N. Y., has disclosed blood fluoride as a function of the fluoride concentration in drinking water. Higher levels of blood fluoride were noted for residents of Newburgh where the fluoridated water supply contains 1 to 1.2 parts per million of fluoride, than for residents of Rochester where the supply contains approximately 0.06 part per million. In this investigation samples of placentae were obtained from the afterbirth of normal patients residing in Rochester and Newburgh, and the fluoride contents determined by the method of Smith and Gardner as described for blood. Table I shows the distribution of the fluoride content of the placental samples as found for the two cities.

Then some statistics are set forth.

Dr. MILLER. Before you go on, Mr. Kleinfeld, I was not sure what you said about the blood content or the hemoglobin content between the two cities. Read it again, please.

Mr. KLEINFELD. Yes, sir. [Reading:]

A previous study of normal blood fluoride concentrations of residents of Rochester and Newburgh, N. Y., has disclosed blood fluoride as a function of the fluoride concentration in drinking water. Higher levels of blood fluoride were noted for residents of Newburgh, where the fluoridated water supply contains 1 to 1.2 parts per million of fluoride, than for residents of Rochester, where the supply contains approximately 0.06 part per million.

Dr. MILLER. At that point then, let me compare the witness' statement on page 6, the statement given today, and I quote:

Blood counts and hemoglobin determinations as well as urinalyses, reveal no differences in the study and control groups.

Dr. AST. That is right.

Dr. MILLER. Now you are in direct variance to the findings.

Dr. AST. Oh, no. Dr. Miller, what I said was that the blood analyses of the children studied in Newburgh were not any different than the children studied in Kingston.

What is stated in this particular paper, I think, refers to placental tissue.

Mr. KLEINFELD. Well, the part I am referring to, I think, Doctor, refers to blood—"blood fluoride as a function of the fluoride concentration in drinking water."

Dr. AST. Let me explain my statement, if I may. Our blood examinations consisted of a blood count and hemoglobin determination. Those are the determinations. Where there is any reason to suspect any change in the blood more detailed blood analyses are made. We have not found any reason for making these.

Dr. MILLER. Doctor, then your examinations are rather superficial.

Dr. AST. I don't think they are considered superficial.

Dr. MILLER. Blood counts and hemoglobin counts, as you and I know, are very simple examinations. These people apparently went into a little more detail, and they did find there was some difference that does not fit into your statement.

Dr. AST. If we considered the blood examination as an entity by itself, I would say that that was a superficial examination on which to make any diagnosis, but——

Dr. MILLER. Yes.

Dr. AST. But taken in context with the rest of the study, which is very comprehensive, I would not consider that that is a superficial study.

Mr. KLEINFELD. I think the situation is this, Dr. Ast—I may be incorrect—the article from which I am quoting refers to the fluoride content of the placental tissue, but they are also referring in this article to a previous study of normal human blood fluoride concentrations.

Dr. AST. Yes.

Mr. KLEINFELD. Made by Smith, F. A.; Gardner, D. E.; and Hodge, H. C., Journal Dental Research, 1950.

Dr. AST. Yes.

Mr. KLEINFELD. I think they are talking about blood.

Dr. AST. Yes.

Mr. KLEINFELD. I will continue, and I quote:

> Thus the increased level of fluoride in the water resulted in a higher concentration of fluoride in the placental tissue, which may be related to the blood fluoride concentration. Also, it should be noted that both the Rochester and Newburgh placental samples had higher concentrations of fluoride than the respective blood samples. Two explanations are suggested for this observation. First, fluoride is an essential trace element. The placenta may act as a concentrating organ for fluoride, to insure that the fetus will have adequate fluoride for the developing tissues. Second, since excessive fluoride is toxic, this organ may be acting as a barrier to prevent more than trace amounts of fluoride from reaching the fetus. How much of this accumulating fluoride passes from the placenta to the fetus is yet to be determined. At any rate, the placental concentrations are not of the order of magnitude to cause deleterious effects in the mother.

Now, Doctor, do you agree that we do not know how much of this accumulating fluoride passes from the placenta to the fetus?

Dr. AST. That is right.

Mr. KLEINFELD. Do you believe that is of any significance?

Dr. AST. No. And may I amplify that? That is based on the fact that we have such a wonderful human laboratory in which to study the effect of water-borne fluoride, and our data from these human laboratories in areas of the United States give us no reason to question the safety factor.

I can refer you to the vital statistics, which I just recently have been able to get, and which should be further studied, in other areas—vital statistics which come from Wisconsin, where they have areas with fluoride content naturally in the water supply and fluoride-free areas. I have here the still-birth rate, the neonatal death rate, and the leading causes for death.

We compare areas such as Green Bay, with 2.5 parts per million of fluorine, with Fond du Lac, 0.5 part per million, and Sherboygan prior to its fluoridation at 0.03.

The total death rate in these areas from all causes was 9.1 in Green Bay, 12.1 in Fond du Lac, and 10 in Sheboygan, with fluoride-free water.

The still-birth rate was 22.5 in Green Bay, 20.7 in Fond du Lac, and 24.1 in Sheboygan.

The neonatal death rate was 25.1 in Green Bay, 22.7 in Fond du Lac, and 22.4 in Sheboygan.

There is no indication that fluorine plays any part at all in either the death rate or the birth rate of children or expectant or pregnant mothers.

Now there is only one study that I know of, and it is an animal study, in which they attempted to determine whether or not fluorine passed through the placenta and through the mammary glands to the developing fetus and infant. That was animal experimentation done many years ago. I am sorry I cannot give you the author. I could dig it out for you if I may take the time. I have it among my papers. In that study it was demonstrated that there was a passage of fluorine through the placenta and the mammary glands, because when the rats in the study were weaned and put on a cariogenic diet, those who came from mothers which had been on fluorine developed less caries than controlled groups. That is the only study with which I am familiar in which that has been studied.

In our human populations, in areas of natural fluorides, there has been very little, if any, evidence of mottled enamel in the deciduous teeth of children reared in areas of natural fluoride waters, which would indicate that high concentrations of fluorine in those areas do not affect the dental tissues during fetal life and in order to affect the dental tissues during the developmental period it would have to be a physiologic reaction.

Mr. KLEINFELD. Dr. Ast, you say you are director of the Newburgh-Kingston caries fluorine study?

Dr. AST. That is right.

Mr. KLEINFELD. I have here volume 40, No. 6, June, 1950, issue of the American Journal of Public Health.

Dr. AST. Would you also give the date on which that paper was presented?

Mr. KLEINFELD. Presented before the dental health section of the American Public Health Association at the Seventy-seventh Annual meeting in New York, N. Y., October 25, 1949.

Are you familiar with that, Doctor?

Dr. AST. Yes; I am.

Mr. KLEINFELD. When was the Newburgh-Kingston experiment started, Doctor?

Dr. AST. The base-line examinations were started in 1944–45. The Newburgh water supply was treated with sodium fluoride beginning May 2, 1945.

Mr. KLEINFELD. On page 716 of this publication the following appears, and I am sure you are familiar with it:

> On May 2, 1945, sodium fluoride was added to Newburgh's water supply to bring its fluorine content up to 1.0 to 1.2 parts per million, while Kingston's water supply remains fluorine-free. It is expected that the study will take 10 to 12 years to determine adequately the efficacy and safety of this caries prophylactic measure.

That was written by you, sir?

Dr. AST. Yes; it was.

Mr. KLEINFELD. Now, when did you change your mind about the fact that it would take 10 to 12 years to determine adequately the efficacy and safety of this measure?

Dr. AST. I haven't changed my mind entirely, since the study is still progressing and will continue for the 10- to 12-year period. But after 4 years of fluoride experience, when we noted the continuing downward trend in the dental caries experience rate in Newburgh, and when we had corroborating evidence from Grand Rapids, Mich., and

Sheboygan, Wis., and Brantford, Ontario, it was deemed advisable then to take advantage, if we could, of this caries prophylactic, since the dental caries picture is of such magnitude that it would not be considered fair to deprive our new generation of children of such benefits which would accrue. Also, since our medical examinations do indicate no reason why this should not be done from a toxic point of view.

Mr. KLEINFELD. On pages 726 and 727 of another article in the same publication entitled "Newburgh-Kingston Caries—Fluorine Study—Pediatric Aspects—Preliminary Report"—are you familiar with that, Doctor?

Dr. AST. Yes; I am.

Mr. KLEINFELD. On those pages the following statement appears, Doctor, and I quote:

> Other special studies are being conducted or planned to answer special questions in connection with the Newburgh-Kingston study. A study is well underway in cooperation with Barnett and McNamara at the New York Hospital in New York City to determine the mode of excretion of fluoride in the urine of children having impaired renal function compared with a group of children of the same age with normal renal function. Another study being planned will attempt to utilize objective quantitative methods for the determination of bone density of children in Newburgh and Kingston.

Do you know whether those studies have been completed, Doctor?

Dr. AST. The urinary excretion work has been done, but unfortunately the data does not lend itself well to statistical significance tests because there are variations in high and low retention. That work is about to be published very shortly.

So far as the bone-density studies are concerned, that has not been done. We were not able to get the kind of equipment needed.

But in regard to bone studies I question whether we could find a better authority than Dr. John Caffey to study the radiographs of our bone pictures, and he has done all of them from the very beginning in 1944 and is continuing to do them. There is no question of interpretation by different examiners.

Dr. MILLER. Mr. Chairman. Doctor, I was interested in what you said about such a variation between the excretion of fluorine in the children with normal and damaged kidneys?

Dr. AST. Yes.

Dr. MILLER. Could you elaborate on that a little more?

Dr. AST. Yes. The children with damaged kidneys did not all show the same picture. There was higher retention, as would be expected, in case of nephritis.

Dr. MILLER. Depending upon the damage in the kidney and the type of renal disease that might be present?

Dr. AST. No. I think with cases of nephritis we find the retention of most of the absorbed elements which pass through the urine. That is one of the characteristics, as you know, Dr. Miller, of nephritis, and so it is not surprising to find there would be greater retention of fluorine in those cases. Whether it is significant or not is another question.

Dr. MILLER. Has that been published yet?

Dr. AST. No. It is in the process of being analyzed now.

Mr. KLEINFELD. I have one last question, Doctor. The final conclusion reached——

Dr. AST. In 1949?

Mr. KLEINFELD. That is right—was as follows, and I quote:

> Final conclusions regarding the possibly systemic effects of fluoride in the dosage employed should not be drawn before termination of the 10-year study.

Has the opinion expressed in this conclusion in 1949 been changed; and, if so, what are the reasons for it?

Dr. AST. Yes. Just before I left I had the privilege of speaking with Dr. Schlesinger, who is senior author in that paper. The reason that we are prepared today—and incidentally that information was passed on to the public health council and the commissioner of health before the State policy was made—was that there is nothing in our data today to indicate any question for alarm; and, while we certainly will continue with studies to get as much detailed information as we can, there is no reason why our present generation of infants should not get the potential benefits from water fluoridation, since there is no toxic effect about which we need be concerned at this time.

Mr. KLEINFELD. The statement was also made in this article, and I quote:

> More refined techniques may also be available in the future in studying pertinent aspects of the problem.

Do you agree with that?

Dr. AST. Sure. We are always ready for progress.

Mr. KLEINFELD. The last paragraph of the article itself, without reference to the summary and conclusions, is as follows:

> The results thus far in the study have disclosed no deleterious systemic effects from the ingestion of fluoride in drinking water in the dosage employed. It must be emphasized, however, that a longer period of observation is required before final conclusions can be drawn. The possibility of demonstrating cumulative effects of fluoride in the final years of the 10-year study cannot be eliminated at this time.

Dr. AST. That is right.

Mr. KLEINFELD. And the people who made this statement then have now changed their mind, you say?

Dr. AST. No. I still think that we have got to continue with our studies. But the possibility of finding potentially deleterious effects is of no consequence at this time, simply because we have our data from Newburgh and Kingston and because we have such overwhelming data from areas where fluorides are found naturally in the water supply.

Dr. MILLER. Mr. Chairman, I would like to ask the doctor a question at that point. Since the studies have not been completed on what happens to children with damaged kidneys, and nothing has been done on adults, how can you say positively that there are no deleterious effects when fluoride is added to water when the studies have not even been completed?

Dr. AST. I should like to refer you then to some vital statistics.

Dr. MILLER. I do not want any vital statistics. I have studied them, and you can prove anything you want to by vital statistics. I want to know what you have done on experiments on kidneys.

Dr. AST. I will have to use vital statistics to give you that information.

Dr. MILLER. Do you have statistics that have been published on children with damaged kidneys?

Dr. AST. No. The point you make is that vital statistics are not going to give you the information you want.

Dr. MILLER. You said you had nothing on those children with damaged kidneys; is that right?

Dr. AST. I can give you vital statistics on death from nephritis.

Dr. MILLER. In children?

Dr. AST. On adults.

Dr. MILLER. On adults who had fluorine in water over a period of time?

Dr. AST. Yes. Green Bay, Wis., has had 2.5 parts per million of fluorine in its water for many years. Fond du Lac and Sheboygan are relatively fluorine-free. Causes for death from nephritis in Green Bay, 51 per 100,000 population; in Fond du Lac, 114.7; and in Sheboygan, 41.3.

Dr. MILLER. I can point to Missouri and Nebraska where we even live longer with no fluorine at all in the water. That is in the tests if you will read that. In Nebraska and Missouri they live longer than they do where they have fluorine.

Dr. AST. Dr. Miller, I do not wish to imply that the presence of fluorine adds to longevity.

Dr. MILLER. Do not try to do it.

Dr. AST. By the same token, nephritis is not responsible for the high or low death rate of a community. It is one of the factors.

The CHAIRMAN. Are you through, Mr. Kleinfeld?

Mr. KLEINFELD. Yes.

The CHAIRMAN. Mr. Abernethy?

Mr. ABERNETHY. No questions.

The CHAIRMAN. Mr. Jones?

Mr. JONES. No questions.

The CHAIRMAN. Dr. Miller?

Dr. MILLER. I think the doctor has a very valuable paper here. He is the one man who knows about fluorine. The only thing that disturbs me, Doctor, is that you started out on a 10-year experiment, and by your own words in 1949 it was to take 10 or 12 years to complete it. I hope you do complete it. You have some very valuable information that will be helpful to this committee and the country when it is all in.

Mr. ABERNETHY. Would you yield for one question there?

Dr. MILLER. Yes.

Mr. ABERNETHY. I would like to ask the witness: What was so appealing or attractive about a 10-year experiment? Why 10 or why 5 or why 15?

Dr. AST. I think I made mention of that in——

Mr. ABERNETHY. The reason I ask—the testimony before the committee on this subject has been wrapped around a specific test of 10-year's duration. Well, what is so sacrosanct or magic about 10 years? That is what I want to know.

Dr. AST. I covered that point in the paper, Mr. Abernethy.

The reason that we selected the magical number of 10 years—and it is not a magical number—is that the presumption was that in order for the fluorine in the water to be effective it had to be ingested during the years of tooth development and that the calcification of the crowns of the teeth would take up to about 8 years, with the exception of the third molars, and it would probably take us until 10 to 12 years to be able to study those teeth. That is the basis for that period.

Mr. ABERNETHY. I see.

Dr. MILLER. I do not think there is any doubt—at least there is no doubt in my mind—but what it is helpful to children in the early years. But in this room I suppose the average age of the people might be 40. Say it is 40. Now what good would it do for a group of people of this age to start to take fluorine in water today? Can you cite any experiments that have been carried out to show it would help us live longer or be healthier?

Dr. AST. I do not know whether it will affect the gentlemen in this room. Probably quite a number of us are wearing some artificial dentures, and I am sure those won't be benefited by fluorine. But we do have some very good evidence that the benefits which accrue during childhood in water fluoride areas are carried over into adolescence and adulthood. What we are thinking of is not the present generation of adults but rather the new generation of adults.

Dr. MILLER. I think that is right. I think it carries over. I agree with you. Evidence points that way. But you would say that this group here, starting to take fluorine in their water, as they will probably here in the District of Columbia if they live here, cannot expect any particular benefits in the years ahead? As far as you know from the studies that have been made, that is right?

Dr. AST. I am not quite prepared to make that statement, Dr. Miller, because when we first started our studies with fluorine it was presumed that the benefits would only accrue if the children took this fluorine from birth through age 8 during the developing and calcifying period. However, our data in Newburgh and data at Grand Rapids illustrate that even those children whose permanent teeth were already present in the mouth when first subjected to fluoridated water have gotten some benefit. Now whether that carries over into the 16- and 20- and 30-age bracket, I don't know, but we do have some evidence.

Dr. MILLER. All right, Doctor. Don't talk too much on one subject. I have a lot of questions I want to ask you.

Mr. ABERNETHY. And he has a lot of answers, too.

Dr. MILLER. He talks too long, talks all around the bush. I want to pin him down to what good, if any, comes to a group of adults starting to take fluoride in water. Is there or is there not any benefit?

Dr. AST. I don't know.

Dr. MILLER. We had testimony by the United States Public Health Service and public-health officials that no studies as to what would happen to adults who might have a damaged kidney or with hypertension, or older people that have chronic diseases, have been made. Have you made any studies, or are you going to make any, at Newburgh on that particular field?

Dr. AST. We are going to study adults. We are going to do a great many more studies as time goes on; yes, but not yet.

Dr. MILLER. You have not had any as yet?

Dr. AST. No.

Dr. MILLER. Do you say then that the studies so far have been with children?

Dr. AST. Yes.

Dr. MILLER. And have you found any children that might have a little more susceptibility to fluorides than others?

Dr. AST. No; there has been no evidence of sensitivity to fluoride. There have been no deleterious effects reported.

Dr. MILLER. Do you think a child in this age group would get the same effect by adding a comparable amount of fluorine to its milk, for instance? Most children drink milk. Could that be done; and, if it was done, could you get the same effect as in water?

Dr. AST. I do not know what the effects would be, but administratively I would think that that would be a very difficult procedure, because a large community, especially——

Dr. MILLER. I did not ask you that, Doctor. I asked you if you took the same amount of fluorides in water whether you would get the same effect if you took them in milk.

Dr. AST. I do not know. There has been no study to that effect.

Dr. MILLER. Well, the fluorides that are ingested in water, if the same amount was placed in milk, would you not say it would have the same effect?

Dr. AST. I do not know.

Dr. MILLER. Well, of course, some of the other men testifying here said it would have the same effect—men who are experts.

Dr. AST. I do not have any evidence to that effect.

Dr. MILLER. Inasmuch as it is just for children, why not put it in milk or water that they drink, if you just want it for the children?

Dr. AST. If I may speak to that point, I think it is administratively very difficult, if not impossible. I do not think the District of Columbia gets its milk from any one area, and whether or not you could control the fluorine content of milk from many areas coming into one central point makes a very difficult administrative job.

Dr. MILLER. Of course it could be done, probably.

Dr. AST. I don't know.

Dr. MILLER. Dr. Scheele, the head of the United States Public Health Service, says he gives his children a little tablet each morning. He must think they get some good out of it, otherwise he would not want to put it in everybody's water.

Dr. AST. I don't think there has been any evidence to that effect.

Dr. MILLER. The United States Department of Agriculture puts out a book, Crops in Peace and War. Members of this committee send it out to their constituents at home. They supply hundreds of thousands of them. In here there is an article on fluoridation. The gentlemen on the Agricultural Committee might give some thought to this. Maybe they ought to strike this section from the book.

I am going to read from page 722:

> The investigations on the fluorine compounds demonstrated that despite their widely different solubilities all were sufficiently soluble and absorbable to provide enough fluorine to mottle the incisor teeth in albino rats. With that as a standard for judging fluorine toxicity, pharmacologists learned that the susceptibility to fluorine toxicity was increased by raising the metabolic rate. The increase in metabolism was induced either by feeding desiccated thyroid or by injecting the thyrotropic hormone of the pituitary gland. The practical significance of the discovery is in its bearing on the public health hazard of fluorine, whether it be in spray residues or in drinking water. Tolerance limits for the allowable amount of fluorine likely to be ingested by the public should be low enough to protect the hyperthyroid individual and the normal one.
>
> The claim that small amounts of fluorine in drinking water or the application of a fluoride, such as sodium fluoride, to the teeth will reduce the incidence of dental caries is undoubtedly correct. Checking dental caries and, in slightly

larger amounts, causing mottled teeth, however, are not the only effects of fluorides. These compounds are enzymatic poisons. For example, the work of the Pharmacology Laboratory demonstrated that the fluoride ion inhibits the enzyme bone phosphatase in young rats and thereby retards calcification of the leg bones.

There is more to it but that is the essential part of the quote of the 1950–51 Yearbook of Agriculture.

I wonder whether you agree with that.

Dr. AST. I should like to call attention to a report by Goldenberg—I can give you the reference on that—published in a foreign journal. I can get you that reference. In it he reported beneficial results from the use of sodium fluoride in the treatment of hyperthyroidism.

Dr. MILLER. You would not agree with the statement in the Agriculture Yearbook that the Congress is sending out all over the country?

Dr. AST. I am not a physician, nor am I a toxicologist, and I wouldn't presume to be able to answer all those questions. I think I had better not attempt to answer it.

Dr. MILLER. Do you know the following men: Floyd DeEds, Robert H. Wilson, and Anthony M. Ambrose?

Dr. AST. I think DeEds has done some work on toxicology. I don't know the others.

Dr. MILLER. The article is written by these three men on Hazards and Potential Drugs.

We did have a number of men before our committee, Doctor, one man who had traveled a great deal, a man by the name of Dr. Hans H. Neumann. Do you know Dr. Neumann?

Dr. AST. I don't know him. I know of him.

Dr. MILLER. He has traveled all over the world, and apparently he has done a lot of studies upon the caries in teeth.

He says:

Perfect teeth can occur in areas without any fluorine in water and are common, actually.

Do you think you have to have fluorine in water to have perfect teeth or near perfect teeth?

Dr. AST. No. I am familiar with Neumann's work, and I wrote a reply to a paper he wrote on this very subject. I do not agree with his thesis. There is nothing in the literature that I find of a scientific nature that Dr. Neumann has published in regard to dental caries other than his observations.

Dr. MILLER. Again, Doctor, let me ask you, do you know of any experiments that have been carried on by the United States Public Health Service or the American Dental Association or the American Medical Association in relation to what happens to old people that may have chronic disease, diseased kidneys, and so forth, as to the effect of fluorine upon that group?

Dr. AST. The only information I have, sir, is from the statistics of mortality rates.

Dr. MILLER. Then would you say that as a Member of Congress—we get a lot of letters, I know the chairman here has, and we cannot answer all of them. If we would say to these municipalities who write to us that the municipalities who contemplate the use of fluorine in their water should understand that experiments are still going on as to fluorine, that evidence to date points to the fact it is helpful to children, but the final result has not been made known as to the

use of fluorine in universal medication when used in water, do you think that is a fair statement?

Dr. AST. No; I do not, sir.

Dr. MILLER. You do not think so?

Dr. AST. No. The benefits——

Dr. MILLER. Would you say the experiments are completed?

Dr. AST. No.

Dr. MILLER. Would it be a fair statement to say the experiments were not completed?

Dr. AST. The full details of the experiments are not completed.

Dr. MILLER. And the full results are not known. Would that be a fair thing to say to that?

Dr. AST. The fullest benefits, though, aren't known from water fluoridation.

Dr. MILLER. And that the United States Public Health Service and others have testified that no experiments have been carried on as to the effects on older people or even pregnant women?

Dr. AST. Yes; that is correct.

Dr. MILLER. And there might be some deleterious effects shown to people with damaged kidneys or pregnant women or those with chronic diseases in the older groups? There might be. I didn't say there would.

Dr. AST. Yes; but what we are getting around to, Dr. Miller, is a question of whether or not we are telling a whole truth or a half truth, and if——

Dr. MILLER. I said might be, I didn't say there would be. I said "might." Would you use the word "might," or do you have some other word? I want to tell these people who are writing to me. Perhaps I should refer them to you and see how you answer them.

Dr. AST. I get a great many letters.

Dr. MILLER. Would it be all right to say there might be some deleterious effects, that experiments are not completed—we are agreed on that—and results are not known, the final results, and there might be some deleterious effects upon pregnant women, old people, and those with chronic diseases?

Dr. AST. If that were qualified by the statement that the likelihood is very remote, and that is based on the endorsement by such health organizations as the American Medical Association, the National Research Council, the American Public Health Association, and the other national organizations which have testified to the safety of this.

Dr. MILLER. Then it would be safe to put another qualification in there, that these organizations have made no experiments, no examination, as to what the effect might be, by their own testimony?

Dr. AST. Yes.

Dr. MILLER. They have said they have carried on no experiments in that field. So why should they endorse it when there have been no experiments in that field? That is what bothers me. You are carrying on some excellent experiments and you say you are going to get into the field of what happens to older people, those with chronic diseases. That is splendid. I hope you do, and I would like to see the results, because I think it is most important. I have even gone so far as to say that they ought to wait until the experiments at Newburgh and Kingston are completed by a man with the reputation of

Dr. David Ast. And those experiments, in your own words, have not been completed. How can I conscientiously say to everybody, "Put fluorine in your water," when we do not know what happens to pregnant women and the class I have referred to?

Dr. AST. Dr. Miller, we are living in a very fast-moving world, as we are well aware, and while I did make that statement in 1949, my observations since then have dictated another turn.

Dr. MILLER. Wait a minute, Doctor——

Dr. AST. And I wish that my later statement was used as an authoritative statement rather than an early statement.

Dr. MILLER. Well, Doctor, did you not say as of today, March 6, 1952, that you were going to carry on some experiments in the Newburgh laboratory?

Dr. AST. Indeed we are.

Dr. MILLER. On what happens to the older group?

Dr. AST. Indeed we are.

Dr. MILLER. And did not you say that the conclusions had not been reached?

Dr. AST. The full evidence has not been reached, that is correct.

Dr. MILLER. Then I would like to tell those people that are going to use fluorine in those waters just those words. I am going to take them right out of the record and say, "Here is the record," and let them make their own decisions.

Dr. AST. But I think, Dr. Miller, that there is other information which should be given to your constituents at the same time.

Dr. MILLER. Statistics like you have there on morbidity and mortality? I could tell them how long they live in Nebraska without fluorine. That is what I will tell them.

Dr. AST. I think your constituents are entitled to the information that there are well over 3 million people in the United States today living in areas where fluorine in concentrations of more than 1 part per million are getting it daily, and where there is no evidence of any detrimental effect. Colorado Springs is a health resort with 2.6 parts per million.

Dr. MILLER. Do you recognize that people that are exposed to little doses of poisons over a period of years build up a resistance and they show no particular harm, but put somebody else down in that particular area and it upsets them?

Dr. AST. Yes; I am quite aware of that.

Dr. MILLER. You are quite aware of it.

Dr. AST. I am also aware of the fact that chlorination has been in effect for more than 40 years, and that while fluorine and chlorine do not have the same reaction, there have never been the kind of extensive studies of chlorine which are being asked for in fluorine.

Dr. MILLER. Do not misunderstand me, Doctor. I agree that fluorine in children is excellent, and I want to continue with it. But I do not think that you have carried on your experiments at your laboratory relative to old people and pregnant women and those with chronic diseases sufficiently far to say that it should be generally used for everyone. It has been shown that the diseased kidney in children holds back the fluorine. That has already been demonstrated. What does it do in an adult?

I think the same thing would occur. I don't know. I hope it wouldn't, but it probably would.

It seems to me in the public interest that we ought to carry these experiments to the conclusion of your 10- or 12-year period before we recommend universal application of fluorine for everyone. I think that would be in the public interest, and that is the only thing I am thinking of.

I can readily say, and I have said to my patients as a doctor, I think fluorine in the water for children is a good thing. I said that 15 years ago when fluorine first came out.

I have endorsed fluorine for youngsters, but I cannot in all conscience say that it is good for people in the older group, particularly those with chronic diseases, and those mothers who are supplying children. There has been ample evidence that it does something to the placenta tissue. The Agriculture Department has recommended that large doses of fluorine not be given to brood sows; in fact, no fluorine at all. The say no fluorine at all should be given to them—not only no large but no small doses even.

If it is important to brood sows, it ought to be important to the pregnant mothers of America.

Dr. AST. Mr. Chairman, I know you are anxious to get me out of the chair, but I would like to make one more point.

The CHAIRMAN. No; I am not anxious at all.

Dr. AST. I thought you were getting impatient.

The CHAIRMAN. As a matter of fact, I would like to ask you one or two questions myself.

Dr. AST. Excuse me, I jumped the gun.

The CHAIRMAN. How does fluorine occur naturally—in what combination?

Dr. AST. I wish I could answer that. Our mental giants in science aren't able to agree on that. We get it principally in water as it passes over igneous rocks in deep wells, but I don't know what compound produces the fluorine ion.

The CHAIRMAN. Is it not combined with calcium for the most part?

Dr. AST. Calcium fluoride is highly insoluble salt, and I would rather expect if it is to be absorbed it would have to be in a more soluble salt.

The CHAIRMAN. That gets right down to what we are talking about. You mentioned a few moments ago that Colorado Springs was a health resort, and the fluorine that occurs in that water is in the form of calcium fluoride; is that right?

Dr. AST. Colorado Springs has 2.6 parts per million of fluorine in its water supply but I cannot say that this is produced by calcium fluoride.

The CHAIRMAN. Generally speaking, everywhere it is calcium fluoride when it occurs naturally?

Dr. AST. I don't think the engineers are agreed on that, Mr. Delaney. I have asked the question of several engineers and chemists, and I couldn't get an answer as to whether it was calcium fluoride or sodium fluoride or any other fluoride.

The CHAIRMAN. I do not think it ever occurs naturally as sodium fluoride, does it?

Dr. AST. I don't know.

The CHAIRMAN. You are not able to answer that question?

Dr. AST. No; I am not able to answer that question.

The CHAIRMAN. In preparing sodium fluoride do they not take the calcium fluoride and then with one of the acids prepare it in that manner?

Dr. AST. But I don't know whether sodium fluoride is found naturally, whether or not we get it out of the soil in rocks as a calcium fluoride, as a sodium fluoride, as one of the other minerals.

The CHAIRMAN. Well, it just occurs to me, if you are using sodium fluoride as an additive there should be some study as to whether or not sodium fluoride occurs naturally, because we are making comparisons with areas in which fluorides appear in the water in a natural state. Is that not right?

Dr. AST. Yes.

The CHAIRMAN. We are using some of those statistics.

Dr. AST. That is right.

The CHAIRMAN. And there is a difference between the solubility of calcium fluoride and the fluoride that is added, which is sodium fluoride?

Dr. AST. Yes; but calcium fluoride at 1 or 2 parts per million is soluble. It is when it gets into the higher concentrations that it is relatively insoluble.

The CHAIRMAN. Now here is something that has occurred to me. There is an additive of chlorine in the water here in Washington. Most strangers are shocked when they first take water containing this. What effect would the sodium fluoride have on the calcium, if you know?

Dr. AST. Sodium is much more active than the calcium in combining with fluorine, so there is no likelihood of the calcium fluoride changing over with the sodium fluoride.

The CHAIRMAN. Then what effect on the chlorine?

Dr. AST. There is no antagonistic action between the fluoride salt and the chlorine. That has been determined.

The CHAIRMAN. What about the taste? Would there be any change in the taste of our water here?

Dr. AST. Only if you add more chlorine. The sodium fluoride at 1 part per million or the fluoride ion from any of the compounds which will be used produces an odorless, colorless, and tasteless solution.

The CHAIRMAN. Sodium fluoride is very toxic?

Dr. AST. Yes.

The CHAIRMAN. A very toxic substance, is it not?

Dr. AST. It is.

The CHAIRMAN. Would its continuous use in pots and pans and teakettles have any effect?

Dr. AST. I do not think so. So far as acute toxic dose to produce symptoms of nausea and vomiting, for example, which are the earlier signs of acute fluoride toxicity, at 1 part per million one would have to drink about 120 quarts of water in a short period of time to get a toxic dose.

The CHAIRMAN. We use it daily in all our cooking and for drinking purposes. If we do that day in and day out for years could that possibly have an effect?

Dr. AST. I don't think so, but I can't answer categorically it will not.

The CHAIRMAN. All right, Doctor, thank you very much for your testimony here today. I know that the committee here is indebted to you because you are one of the witnesses who has actually conducted experiments and gone to great lengths in your attempt to bring sufficient evidence before the American public of the benefits of fluorine in drinking water.

Dr. MILLER. May I add a word, Mr. Chairman?

The CHAIRMAN. All right, Dr. Miller.

Dr. MILLER. I just wanted to say, when you complete your experiment on what happens to the older group and those with chronic diseases I hope you will send me some material on it. I was very much interested.

Dr. AST. Thank you. I will keep you posted from time to time.

Mr. ABERNETHY. I have one question, Mr. Chairman. Doctor, is it not reasonable to assume that experiments will never be completed in the use of any chemical or substance; is that right?

Dr. AST. Thank you, Mr. Abernethy, that is the very question I was hoping would be asked. We will never be through with our experiments and we will always have questions to answer.

Mr. ABERNETHY. There will always be some possibility of some question being raised about the use even of drugs and chemicals that are now on the market and have been for a number of years?

Dr. AST. I think that is a correct statement.

The CHAIRMAN. And this committee could never complete its study, could never possibly complete its study.

Dr. AST. I do not think we will ever be able to say, "finished". If we do, our progress will simply be stopped.

The CHAIRMAN. We have to call a termination at some point.

Dr. MILLER. With that, I agree, Mr. Chairman, thoroughly. But I do say there ought at least to have been a start on the examination as to what happens to adults. There has not been a single thing done. In his words, he is just starting it. I think that should be done before we order a universal medication of fluorine in water.

The CHAIRMAN. I am thinking of our over-all picture.

Dr. MILLER. Children, yes, excellent.

The CHAIRMAN. We have no more planned meetings at this particular time, but I think every member of the committee realizes that we have not even scratched the surface.

Dr. MILLER. That is right.

The CHAIRMAN. That we could go on and on for many, many years and each day something new would develop. But we have to terminate.

The purpose of this committee, of course, is to conduct these hearings so that we can better legislate, if legislation is needed. And that is what we are attempting to do now. We realize that this study of chemicals in foodstuffs can never, never be completed. New things happen every day.

I think Mr. Jones has a question.

Mr. JONES. I do, Mr. Chairman. I was going to ask the doctor if this was not a fact: That if the reason those studies have not been made that Dr. Miller has indicated should be made was possibly due to the fact that your vital statistics indicate that in communities where the water does have fluorides and those where they do

not have fluorides, the condition is not so different as to think that there would be the importance of making those tests? Would that have something to do with it?

Dr. AST. That is correct, sir.

The CHAIRMAN. Thank you, Doctor.

Dr. AST. May I just make two points that have been raised that I haven't had a chance to answer? I will try to make them very short.

The CHAIRMAN. Yes.

Dr. AST. The point has been made that the water fluorides benefit children, and the emphasis is all on children. I should like to get into the record that our present and our next generation of children will be the following generations of adults, and that they carry over these benefits into adulthood.

The second point is with regard to nephritis. Much has been said about the potential dangers of fluorides with nephritis. Patients with nephritis are sick people and should be under the care of competent physicians. The physician prescribes a diet for that patient and prescribes medication.

While I do not concede that fluorides in water may have any effect on a nephritic patient, I do say that if such should be the case, there would be every reason why that physician could prescribe distilled water for his patient, and frequently does, rather than to hold up the progress and the potential benefits to untold millions of people in this country, because we have a question which still has to be resolved.

The CHAIRMAN. Thank you, Doctor.

Dr. AST. Thank you.

The CHAIRMAN. Call the next witness, Mr. Kleinfeld.

Mr. KLEINFELD. Dr. Heyroth.

The CHAIRMAN. Give your name and address to the reporter.

Dr. HEYROTH. Francis F. Heyroth, Kettering Laboratory, College of Medicine, University of Cincinnati.

(The oath was administered by the chairman.)

The CHAIRMAN. Proceed, Mr. Kleinfeld.

TESTIMONY OF FRANCIS F. HEYROTH, M. D., REPRESENTING NATIONAL RESEARCH COUNCIL AD HOC COMMITTEE ON FLUORIDATION OF WATER SUPPLIES

Mr. KLEINFELD. Do you have a prepared statement?

Dr. HEYROTH. I have the following brief statement.

Mr. KLEINFELD. Do you have copies for the committee?

Dr. HEYROTH. I don't have of this. This is merely a qualification statement.

Mr. KLEINFELD. Will you please read your qualifications?

Dr. HEYROTH. My name is Francis F. Heyroth. I received the degree of M. D. in 1925, and Ph. D. in 1929, both from the University of Cincinnati. For 2 years I was a medical fellow of the National Research Council, studying at Harvard Medical School, and the University of Upsala, Sweden. At present I am associate professor of biological chemistry, College of Medicine, University of Cincinnati, and associate professor of industrial toxicology and assistant director of the Kettering Laboratory of the department of preventive medicine and industrial health, University of Cincinnati. I am also a member of the Cincinnati Board of Health.

My interest in chronic fluoride intoxication has been largely in relation to the condition as it may occur among workmen exposed to dusts arising from the manufacture or handling of fluorides in the form of cryolite, or superphosphates, or to vapors of hydrogen fluoride. For a number of years my associates have been investigating the storage and physiological effects of fluorides when ingested over long periods by animals or by man, and we have assembled a bibliography of several thousand references to the subject. When, a little over a year ago, a delegation from the Cincinnati Public Health Federation requested the local board of health to approve the fluoridation of the Cincinnati water supply, the board deferred action until I could review our past work and the work of others. The results were presented as a report to the board, at the conclusion of which I introduced the following motion:

I move that the board recommend to council that the water works be directed to adjust the fluoride content of the city water to that which is optimal for dental health, by the addition of a fluoride-containing compound of such nature and in such amount as the board may specify and in accordance with such procedures and with such analytical controls as may be prescribed by the board to insure the safety of the public and of the workmen engaged in the process.

This was carried by the board, and council has recently taken favorable action. I subsequently presented portions of this report dealing with the systemic toxicity of fluorides to a meeting of the National Research Council's Ad Hoc Committee on Fluoridation of which I was a member. This committee has subsequently condensed the gist of its deliberation in the form of a brief report, approved by all participants.

Dr. MILLER. At that point, what experiments did you carry out as to the toxicity of fluorine on animals or human beings?

Dr. HEYROTH. Both. I have that in the statement. I will come to that in a moment, if I may.

Dr. MILLER. All right.

Dr. HEYROTH. I have both of these reports here, and wish to submit them for the record. Now, if it is desired, I can read the six-page report of the National Research Council.

The CHAIRMAN. Have you extra copies of those reports?

Dr. HEYROTH. I have only one copy left of the National Research Council's report, but Mr. Gardner informed me yesterday that they would be submitted to the committee.

Mr. JONES. We have the copy here.

Mr. KLEINFELD. Pardon me. May I suggest that the reports which Dr. Heyroth mentioned be made a part of the record?

The CHAIRMAN. I have no objection. Unless some other member has objection, we will order them in.

They do not refer to anyone by name?

Mr. KLEINFELD. These are reports endorsing the fluoridation.

The CHAIRMAN. I have no objection, unless other members do. It is so ordered that they will be made a part of the record.

Dr. HEYROTH. Now the other report is the one submitted to the Cincinnati Board of Health, and I have 12 copies of that here for distribution, if you do not have them.

Dr. MILLER. At that point, I want to read here. Part of your report says this, sir:

While some aspects of water fluoridation are still in the experimental stage, its application has been shown to be technologically practical and economically feasible. However, it remains to be determined by each municipality contem-

plating installation of this procedure (1) what benefits may be exacted, (2) what the potential liabilities are. After reviewing the available evidence your committee believes that the following are principal considerations—

and so forth.

In other words, you say in those words that experiments are still being carried on; the exact effect we do not know.

Dr. HEYROTH. No. The first part of what you read is——

Dr. MILLER. Experimental stage.

Dr. HEYROTH. What page?

Dr. MILLER. Page 1. You say, "In the experimental stage," in the middle of the first paragraph—"While some aspects of water fluoridation are still in the experimental stage."

Dr. HEYROTH. That is right.

Dr. MILLER. That is what you wanted to say?

Dr. HEYROTH. Yes.

Dr. MILLER. In other words, you have not found the answers to some of the experimental things carried on?

Dr. HEYROTH. Well, I think, as was brought out just a few moments ago in Dr. Ast's testimony with regard to some questions, it was pointed out that in a question of this sort we never get all of the answers.

Dr. MILLER. All right.

Dr. HEYROTH. It is going to take years to do that.

The CHAIRMAN. Complete your statement, Doctor.

Dr. HEYROTH. This Cincinnati report which is being passed out to you is 16 pages, and would take considerable time to read.

The CHAIRMAN. Yes.

Dr. HEYROTH. If there are any questions raised on this report——

The CHAIRMAN. We have not had an opportunity to look at either report until this very moment. So if you will go on with your prepared statement.

Dr. HEYROTH. Then I will read this National Research Council report.

The CHAIRMAN. The one you were on originally.

Dr. HEYROTH. I finished that.

The CHAIRMAN. Thank you, Doctor.

Mr. KLEINFELD. You are representing here the National Research Council, are you not?

Dr. HEYROTH. That is right.

Mr. KLEINFELD. And the statement represents the official position of the National Research Council?

Dr. HEYROTH. That is right. It is six pages. Do you wish all of it read?

The CHAIRMAN. Start it and we will go as far as we can.

Dr. HEYROTH. This committee—that is the committee of the Research Council—was convened and directed to express its judgment as to whether, on a basis of a review of the present status of scientific knowledge, supplementing the fluoride content of public water supplies for the partial prevention of dental caries is a desirable and safe procedure from a physiological viewpoint. Specifically, it has been advocated, where necessary because of the deficiency of this element, that the fluoride content of the public water supplies be adjusted to insure a mean content of approximately 1 part per million of fluorine. While some aspects of water fluoridation are still in the experimental

stage, its application has been shown to be technologically practical and economically feasible. However, it remains to be determined by each municipality contemplating installation of this procedure (1) what benefits may be expected, and (2) what the potential liabilities are.

As to that first, I might interpolate that the benefits to be expected will vary with the municipality because some municipalities may have no fluorides in the water, others may have one-tenth of a part per million, others may have two-tenths, others three-tenths, and so on. Now there would be less caries initially present before fluoridation in those that have some fluorides, say, a half a part per million, than there would be in those that have none. So that when you bring it all to 1 part per million by adding fluoride you would get less benefit in those communities that have normally some fluoride than you would in those communities that had none.

Do you understand what I mean by that?

The CHAIRMAN. Oh, yes; very well. And the food, of course, may play a part.

Dr. HEYROTH. The foods have a part but they have a relatively minor part in most cases.

After reviewing the available evidence, your committee believes that the following are the principal considerations, briefly stated, upon which judgment must be based.

1. Under normal conditions of living, fluorine is a trace element in human nutrition (McClure, 1951). Minute amounts are absorbed from certain foods and drinking water and, to a limited extent, are retained by dental and osseous tissues. The quantity of fluorine ingested in food is a relatively unimportant variable; the average diet contains 0.2 to 0.3 milligram daily. Of greater import is the variable quantity ingested in drinking water. Many of the public water supplies in the United States, particularly those of the large cities, derived from rivers, lakes, and ponds, are practically fluoride-free; others contain from traces to 1.5 parts per million fluorine as fluorides. A number of supplies (Hill and others, 1949), particularly those obtained from deep wells and aquifers irregularly distributed in various parts of the country, contain from 1.5 parts per million up to 7 or 8 parts per million, very rarely more.

There was one community at Bauxite, Ark., some years ago that had 14. They have changed their water supply there now.

I believe that some prior witness has introduced testimony in regard to the number of people who had drinking water in various parts of the country where there was more than a certain amount of fluoride, and I won't take that up.

2. From the epidemiological investigations of Dean (1946), there is convincing evidence that within certain limits there is an inverse relationship between the natural fluoride content of drinking water and the frequency of dental caries in children dependent upon these supplies. The most useful index of the amount of caries is the number of decayed, missing, and filled permanent teeth—DMF—per child, per 100 children, or per 100 permanent teeth, at specified ages. Dean's original observations were based upon 7,257 selected white school children aged 12 to 14 in 21 cities of four States. The prevalence of caries—DMF—was greatest in those children who had used continuously from birth the public water supplies which were fluoride-

free. The prevalence was progressively less in comparable children reared in cities with public water supplies having a fluoride content up to approximately 1 part per million. Beyond this concentration there was little, if any, advantage. Children reared in cities where drinking water contained approximately 1 part per million of fluorine experienced only about one-third as much dental caries as those reared in cities whose water supplies were fluorine-free.

The CHAIRMAN. What is your authority for that statement?

Dr. HEYROTH. The work of H. Trendley Dean of the Public Health Service.

The CHAIRMAN. Yes.

Dr. HEYROTH. Published in 1949. These basic observations have been confirmed and extended by investigators in this and other countries. Similar observations have been made not quite so extensively, in England and elsewhere.

3. The caries-preventive effect of adequate fluoride intake is principally conferred upon children when the dentine and enamel of the permanent dentition are being formed, that is, from birth up to about the twelfth year. There is evidence that this increased resistance to dental caries is carried over to some extent into later life, so that at least there is a delay of several years in the incidence of caries (Forrest, 1951). A recent detailed epidemiological study of adult populations (Russell and Elvove, 1951) considerably extends knowledge in this field. These observations show that marked caries-inhibitory effects of fluoride waters are operative in the 35-, 39-, and 40- to 44-year-old groups.

That is recent work that some of the dentists presented at the meeting of the committee, which was deemed by the dental group acceptable. I am not in a position to judge that work as I am not a dentist.

4. A considerable number of experimental studies have been conducted in the laboratory to explore the inhibition of induced experimental caries in rats and hamsters by fluorides and to explain this action. The results give consistent support to the concept of a relationship between human caries and fluorides (McClure, 1951). While it appears probable that caries resistance is associated with the incorporation of fluorides into the tooth structure, the exact mechanism by which it is mediated is unknown. The causes of caries are only partially understood.

5. The margin between the optimal quantity of fluoride in drinking water which is required for maximal benefit in tooth development and the amount which produces undesirable physiological effects is sufficiently wide to cause no concern. The most sensitive indication of the latter is the enamel defect of the permanent teeth known as endemic fluorosis, or mottled enamel. The epidemiological studies of Dean (1942), based upon examination of 5,824 white children in 10 States, showed a direct correlation between severity of the manifestations of mottled enamel and the increasing fluoride content (up to 5 parts per million) of the water supplies upon which they were dependent. At approximately 1.0 part per million, less than 10 percent of children show the least detectable evidence of disturbances in enamel formation, which are not visible except to the trained eye of the examining dentist. Beginning at about 2 parts per million, an increasing proportion of children have mottled enamel of a grade that

is easily apparent. While such teeth are caries-resistant, they are esthetically objectionable.

6. While the safe level of fluoride concentration to afford a maximum caries-preventive effect without mottled enamel is approximately 1.0 part per million, it varies somewhat with climatic and other factors and must be ascertained for each general area (Dean, 1951). For practical public-health purposes, it has been proposed that a safe level has been reached when not more than 10 to 15 percent of children age 12 to 14 years, who have used water supplies since birth, and who have been examined under standard conditions, show the mildest detectable type of mottled enamel. Under the climatological conditions prevailing in the Chicago area, where the mean annual temperature is about 49° F., this uppper limit has been reached by domestic water supplies containing approximately 1.0 to 1.5 parts per million fluoride. On the other hand, in the vicinity of Moultrie or Brunswick, Ga., with a mean annual temperature of 68° F., the upper level has been found to be associated with water supplies containing only 0.5 to 0.7 part per million.

I might interpolate that in Charlotte, N. C., they make an adjustment in the amount that they add to the water seasonally—more in the winter than in the summer. At the higher temperatures in the summer more water is consumed.

7. There is an extensive literature on the pharmacology and toxicology of fluorine and its compounds. This has been reviewed by McClure, myself, Cox, and Hodge, and by a number of others—DeEds, Greenwood, and several others.

Only those parts of it which deal with the cumulative action of fluorides are pertinent to the question of the safety of fluoridation. That is acute intoxication, which is something that doesn't disturb us.

Chronic fluoride intoxication characterized by bone, joint, and other tissue changes has been the cause of impaired skeletal function in Danish workmen exposed to fluoride dusts as an occupational hazard. The authority for that is a monograph on fluoride intoxication published by Roholm in 1937.

The presence of concentrations of fluorides in excess of 5 parts per million in water supplies in certain parts of the world has been reported to have given rise to a number of cases of chronic fluorosis, but the reported data are inadequate to establish the threshold concentration at which storage may be expected to occur to a potentially harmful extent.

That is one of the points which we wish to determine and on which we are doing some work at present.

A radiologic survey at Bartlett, Tex., where the water contains 8 parts per million revealed an increased bone density not associated with functional impairment in 11 percent of those examined. I might add there that that work is unpublished, the work of Dean of the Public Health Service. It was introduced in the testimony at the hearings for the establishment of a tolerance for insecticidal fluorides some years ago—1944.

Roentgenologic examinations of a limited number of persons living in areas where the water contained from 1.2 to 3 parts per million revealed no evidence of fluorosis. That was work done in Illinois by Hodges, not the same Hodges referred to in the prior testimony.

That is 1.2 to 3 parts per million, in some 86 people examined roentgenologically they found no evidence of any chronic fluorosis or alterations of the bones.

The fluoride concentrations in the urine of normal teen-aged boys and young men closely approximate numerically those in their drinking water in regions where the water supplies contain from 0.2 to 4.7 parts per million. That is the work of McClure, and it was done on boys in high school and inductees in draft centers and draft stations in various parts of the country where the water contained known amounts, and where the inductees had been living for their life in areas where the content was known. Other draftees were excluded if they had just come into the area recently.

Fluorine balance studies furnish additional evidence that the human body eliminates the major portion of food- and water-borne fluoride when the quantities ingested do not exceed 4 to 5 milligrams of fluoride daily (McClure, 1951), although the daily ingestion of 6 milligrams led to demonstrable storage. That is in the work of my associates, Machle and Largent, some years ago.

In the accumulated experience there is no evidence that the prolonged ingestion of drinking water with a mean concentration of fluorides below the level causing mottled enamel would have adverse physiological effects. Since the water supplies in various parts of the country contain considerably greater amounts, it is desirable that epidemiologic surveys of the incidence of chronic fluorosis be made in those regions, and that further balan e studies be undertaken in order to establish the facts in regard to the storage of fluoride at moderately elevated levels of intake.

We are doing that in connection with two subjects now who have been living for all of their lives, and they are in their sixties, in the town of Bartlett, Tex., where 7 to 8 parts per million are present naturally in the drinking water. Those people are in perfectly good health at this age. They also happen to shown no roentgenologic evidence of fluorosis.

8. In 1945, studies were begun to ascertain whether the adjustment of the fluoride content of a public water supply to the optimal level with commercially available fluorides would confer the same caries-inhibitory effects as do waters which carry the same concentrations of fluoride naturally.

That point should be emphasized a bit. That is the real purpose of the experiments at Newburgh and Sheboygan and the rest of the places that have been named—to see whether it is true that sodium fluoride, hydrogen fluoride which is used at Madison, Wis., some silico-fluoride or anything else, would have the same effects if added to the water as that which occurs naturally.

I believe you asked a question related to that some time before.

Preliminary analysis of the first 4 years is now available on two studies in which the observations were carefully controlled: (1) The Grand Rapids, Muskegon, Aurora study (Dean and others, 1950); (2) the Newburgh, Kingston study (Ast and others, 1950–51).

Beginning in January 1945, sodium fluoride was added to the Grand Rapids water supply in sufficient quantities to insure continuous maintenance of a level of about 1 part per million. In order to establish a base line of dental caries experience prior to fluoridation, 19,680 children with history of continuous residence in Grand Rapids, Mich.,

were given a complete dental examination. In addition, 4,291 children were examined in Muskegon, Mich., a city which derives its fluoride-free water supply from the same source as does Grand Rapids, that is, from Lake Michigan. An additional 5,116 children were examined in Aurora, Ill., where the community water has contained 1.2 parts per million of "natural fluoride" for years. Data from examinations conducted at Grand Rapids and Muskegon during the autumn of each year since 1945, that is, five yearly examinations since fluoridation was begun, have been tabulated. These examinations were made on representative children from the kindergarten, first, fourth, eighth, and eleventh school grades. In Grand Rapids, there has been a reduction in caries experience in the permanent teeth of children examined in 1949 as compared with the rate expected on the basis of the 1944–45 examinations, particularly in the younger ages. The apparent amount of reduction in the DMF rate per child at ages 6, 9, 13, and 16 years, was approximately 51 percent, 36 percent, 17, and 12 percent, respectively. Concurrently, there has been a slight decline in the caries rates reported by Muskegon with its fluoride-free water supply but it is relatively small and inconsistent, 22 percent in the 6-year-olds and 28 percent in the 7-year-olds. This is unexplained. In the 5-, 6-, and 7-year-old groups at Grand Rapids the DMF rates now approximate those of comparable groups of children in Aurora. Preliminary analyses of of the 1950 dental examinations at Muskegon and Grand Rapids indicate that the observed dental caries experience at Muskegon is again similar to that recorded in the 1944–45 base line. At Grand Rapids, a further reduction in dental caries prevalence was observed.

In another study, beginning in May 1945, sodium fluoride was added to the water supply of Newburgh, N. Y., so as to provide a content of 1.2 parts per million, while the Kingston, N. Y., supply was, and has continued to be fluorine-free. At the end of 4 years of fluoride treatment of Newburgh's water supply, analysis has been been made of the data on dental caries experience both of deciduous and permanent teeth of approximately 3,200 school children 5 to 12 years old in Newburgh, and 3,100 children of the same age in Kingston. In brief, the investigators conclude that the DMF rates among permanent teeth of the 6- to 12-year-old children in Newburgh show a consistent downward trend after 4 years of fluoridation, whereas the DMF rates in the control city of Kingston show no changes. The reduction in Newburgh is from 20.6 DMF per 100 permanent teeth to 13.9, or a reduction of 32.5 percent. The rate in Kingston remained at 20.2 DMF per 100 permanent teeth. Since the first permanent molars are the teeth most affected by dental caries, a special analysis of the condition of these teeth was made. The number of caries-free first permanent molars increased in Newburgh, after 4 years of fluoride exposure among 6- to 9-year-old children, from 59 per 100 molars to 77. The number of caries-free permanent teeth among Kingston children of the same age remained essentially unchanged.

From these two studies, therefore, it appears that the adjustment of the fluoride concentration to optimal amounts in a water supply previously deficient in this element has resulted in considerable reduction of caries in children. Just how great a reduction may be effected ultimately will have to wait upon a longer period of observation. Reports from other cities which have installed this procedure tend to corroborate the studies mentioned above (Hutton and others,

1951; Bull, 1949–50; Erlenbach and Tracy, 1946; 1948; Hill and others, 1950). Continued observations, however, are essential to establish the degree of effectiveness in higher age groups.

9. In the control studies to which reference was made in the preceding paragraph, sodium fluoride—NaF—was added to the water supplies. Assuming that the availability of fluoride ion is the same, the use of sodium silico-fluoride—fluosilicate—Na_2SiF_6—should result in considerable savings. On the basis of experimental studies, the fluorine in sodium fluoride and sodium fluosilicate produce similar physiological effects upon rats (McClure, 1950) and are equally effective in inhibiting the development of induced dental caries in rats (Zipkin and McClure, in press). Accordingly, it is inferred that this would apply to human experience as well, although this has not yet been demonstrated. Other considerations being equal, for reasons of economy the cheaper material—fluosilicate—is recommended. In the case of smaller public water supplies, however, other factors, such as available space, handling hazards, and equipments preference, will determine the choice of the compound used.

10. The statement that fluoridation of water supplies reduces tooth decay 65 percent is postulated on an expectancy for a population using a fluoride-free water supply. When a public water supply naturally containing 0.4 to 0.5 parts per million, of fluoride is adjusted to the optimal level—1.0 part per million—the reduction in dental caries prevalence obviously would be less. Upon the basis of information at present available, it is not possible to predict how much reduction of caries will be apparent in the adult population. Other factors—genetic, dietary, bacteriologic, and the availability of dental services, et cetera—affect the prevalence of caries and vary in every community. Fluoridation is a partial caries-control procedure and does not eliminate the need for other dental-health measures.

11. The promotion, initiation, supervision, and proper operation of the fluoridation of public-water supplies is a responsibility of the State department of health, acting jointly through its bureau or division of dental health and through the division of public-health engineering with the collaboration of the dental and medical professions. Suitable local plans for dental health surveys before fluoridation and periodic evaluations should be set up by the dental public-health program director. These surveys should provide data suitable for calculating an index of caries attack and an index of the frequency and severity of dental fluorosis—mottled enamel. Engineering aspects of fluoridation, such as tests to determine the fluoride content of the water, safety provisions, training of operators, et cetera, should be covered by State regulations. The statement of policy and procedure formulated by the American Water Works Association—1949—will be acceptable to most State departments of health. Municipalities contemplating the installation of fluoridation should look to the State health department for expert guidance. Many small communities would be unable to maintain satisfactory fluoridation practice without assistance. There are many so-called automatic plants applying chlorination which allegedly do not require full-time attendance of a water-works operator. Many have very limited laboratory facilities, or lack technical personnel to make accurate chemical determinations of fluoride content. Ultimately, State or regional labora-

tories will have to take over routine chemical examination of samples along with established bacteriological control. Provision for periodic visits by a State sanitary engineer cannot be considered adequate supervision.

Summary and conclusions: Under normal conditions of living fluorine is a trace element in human nutrition. A variable and important source is drinking water. Many of the public water supplies in the United States are deficient in this element. Children dependent upon such supplies have a high dental-caries-attack rate as compared with children living in cities having water supplies containing about 1 part per million of fluoride. The advantage of the latter group is considerable and is of the order of one-third to one-half as much caries. The caries-preventive effect of adequate fluoride intake is principally conferred upon children up to about the twelfth year of life, during the period when dentine and enamel of the permanent dentition are being formed. This increased resistance to dental caries is carried over into later life to an appreciable degree. The results of experimental studies conducted in the laboratory give consistent support to the concept of the inhibitory effect of fluoride on the caries process.

Perhaps I might interpolate there some of the evidence on which the statements as to safety are based. That will be found in the Cincinnati report.

I might point out that it comes from several independent sources. One would be annual experimentation in which long-term feeding experiments have been carried out, in which the fluoride of one or another type has been added to the diet, food, but not the water, usually, of animals over long periods of time. And, of course, in such experiments, if the level is high enough harm will result. As you cut the level down that becomes less and less.

Any effects on the kidney or on the ability to grow, or the general appearance of the animal and so on will show themselves only at levels considerably higher, very far higher, than those that are required in order to produce fluorosis or an effect upon the teeth in the experimental animals.

That is where we got the idea of the margin of safety between that which causes systemic damage and that which causes dental damage.

Since the dentists are all eagerly watching the program in any city which undertakes fluoridation, they are on the lookout for any possible mottling and, of course, the long-term epidemiologic experience has shown that this never occurs except to the very limited extent that I mentioned at 1 part per million.

The CHAIRMAN. Doctor, suppose we went on for 15 or 20 years. I do not know how much the system would be able to absorb. In 15 or 20 years, a generation or two generations, then it is possible that mottled teeth might come more frequently than we see them now?

Dr. HEYROTH. No. They have gone on in the areas in which the water is naturally contaminated with fluoride. The people have lived there for many, many generations. If they are high fluorides, they all show mottling. If they are low fluorides, 1.3, something like that, as they are in some of the Illinois areas, they do not.

The CHAIRMAN. It is true, too—or am I right in assuming that fluoride in its natural state is in combination with calcium?

Dr. HEYROTH. In the water?

The CHAIRMAN. Yes.

Dr. HEYROTH. We don't know what it is in combination with and there is no way to find that out.

The CHAIRMAN. You are familiar with this sodium fluoride. How is that prepared in a laboratory?

Dr. HEYROTH. Sodium fluoride?

The CHAIRMAN. Yes.

Dr. HEYROTH. Well, it could be prepared, as Dr. Ast said, by starting with, well, any one of a number of sources. You could start with superphosphate. That has it.

The CHAIRMAN. What is fluorine itself? Is that a gas?

Dr. HEYROTH. Fluorine—spelled "i-n-e" is a gas.

The CHAIRMAN. That is a gas?

Dr. HEYROTH. Which we are not concerned with at all because we are not putting fluorine in water.

The CHAIRMAN. Get to the water now.

Dr. HEYROTH. Chlorine is a gas and fluorine is a gas. Sodium is combined with chloride to make sodium chloride, which is common table salt. When it dissolves in water it breaks down to form two parts—the one called the sodium ion, which has a positive electric charge, and the other the chloride ion which has a negative electric charge. Neither of those ions bear any chemical or physical relationship to the chlorine gas or metal sodium.

The CHAIRMAN. Where do we find fluorides in the ground?

Dr. HEYROTH. In many minerals in many different combinations, and you can make sodium fluoride from any of those if you use the right process.

The CHAIRMAN. Just how do you make it?

Dr. HEYROTH. I am not familiar with the technical processes. You could make it in a laboratory by starting with calcium fluoride, adding an acid, distilling the hydrofluoric acid off, collecting it and neutralizing it with sodium hydroxide.

The CHAIRMAN. Is that the common way of making it?

Dr. HEYROTH. I do not believe so. It may come as a byproduct in aluminum refining where they use large quantities of sodium aluminum fluoride, called cryolite, a naturally occurring mineral. You might get it from that. You might get it from superphosphate rocks where it occurs in a form unknown to me, in fair amounts, but it could be recovered by process with which I am not familiar.

The CHAIRMAN. While we are on that subject, you are familiar with our supply of water here in the District; are you?

Dr. HEYROTH. No; I am not.

The CHAIRMAN. Well, if you were here for any length of time you would know that we have a quantity of chlorine in the water. In your opinion, Doctor, would a combination of fluorine and chlorine have any effect?

Dr. HEYROTH. No effect whatever in the concentration in which these things are used.

The CHAIRMAN. There would be no clash?

Dr. HEYROTH. No, no clash at all.

Now that was one line of evidence experimentally.

As to storage, we might make experiments, and we have done this in our laboratory on man. We have had some human voluntary sub-

jects who have ingested daily added amounts of sodium fluoride, or let's just say of fluorine as sodium fluoride.

In some experiments we have added it as calcium fluoride, in some as bone meal, and in some in other forms, to their diet daily over periods of some weeks, sometimes 2 or 3 weeks, sometimes 14 weeks.

These subjects have collected duplicate samples of all of the foods that they eat and of all of the water and other beverages that they drink. That is, if a person has a meal in a restaurant he buys an extra meal, carries a jug with him and puts that in the jug, so that we know what the dietary intake is. Then he takes a capsule containing sodium fluoride, takes three of them per day, to get 6 milligrams, say, or in some cases 18, and in a few cases even 36 milligrams per day.

Then all samples of the feces and all samples of the urine are collected. That is done over months. And the balance between the intake and the output is studied in that way.

Now the amount that is excreted in the feces is deducted from the intake. The rest of it we say is absorbed into the body from the digestive tract into the blood and into the tissues. Then some of that is excreted in the urine. We measure that.

Now what we do not account for of the amount absorbed, what we don't pick up in the urine, we say is stored in the bones. That is not quite correct. Some of it is excreted through the lungs, perhaps a bit, not much, in the air. Some of it is put out in the perspiration, and we have no good way technically of measuring that. Some attempts have been made to do that and a certain amount has been found by McClure in some of his experiments. We have not done it in any exhaustive fashion.

In that way we can begin to say how much storage occurs at definite periods. We have quite a mass of evidence pertaining to that, some of which, not all of it, is incorporated in here, because we have a reasonably good foundation of information on that.

It is beginning to appear both in animal experiments of Mitchell and Lawrence, and in our own experiments, that when the ingestion of added fluorides occurs over periods of time, then more absorbed fluoride may be excreted in the urine than appeared at first at the beginning of the experiments. That is, as the bones become laden they take it up more difficultly so it is harder to get storage after a long period of time. I say only that we have indications at present that that is the case. We are not sure of that.

To be sure of that we are working on the subjects from Bartlett, Tex., who for their lifetime have been using water with eight parts per million, and we are going to make balance studies of the same sort on them to see what they are doing.

The CHAIRMAN. As you say, Dr. Dean conducted an experiment there and he found that 11 percent of the——

Dr. HEYROTH. Radiologic.

The CHAIRMAN (continuing:) People had bone impairment.

Dr. HEYROTH. No; they had increased density of the bones.

The CHAIRMAN. Increased density, rather.

Dr. HEYROTH. That was detectable only on the X-ray, but not very marked, and some people who have seen some of those X-rays don't even agree it is there.

On the other hand, none of those people had any impairment of the skeletal function, that is, they didn't have arthritis; they were able to move their bones and joints without any trouble.

Some of the Danish workmen who had inhaled dust that had large amounts of fluoride in it over the years did have some impairment of skeletal function. They got what they call poker backs, stiff backs; not many of them, but a few did.

That is the condition we are looking for, you see, and that is the condition we must assure ourselves will not occur as a result of fluoridation.

Now, that human experimentation is the second line of evidence.

The third is the epidemiological observations in areas in which the water has naturally contained fluoride and people have used that water for years, for their lifetime. We don't have as much evidence there as we would like, and we are trying to stimulate more work of that sort being done.

The one is the work of Hodges and his group, radiologic in nature, in the regions in Illinois where the amounts aren't great—1.3 up to 3 parts per million in two cities. They have shown nothing positive, that is, no harmful effects.

The other is that which we have just mentioned in Bartlett.

Now, then, there is to my mind a more significant and a better approach still, and that is the one of industrial toxicology. There are factories in this country where men in their sixties who, during 25 or 30 years of employment have had a chance to ingest dusts or to inhale dusts that contained considerable amounts of fluoride. So those men have been surveyed, not for the purpose of this question of fluoridation of water, but for the purpose of studying industrial health.

They have been examined radiologically. They have been examined clinically for any signs of ill health. There are not many cases of positive fluorosis. There are some where there have been fair amounts inhaled over the years. There are a few.

In this country there has been no impairment of skeletal function, although there are radiologic signs of the disease.

Now what one would want to do is to correlate the incidence of any radiologic change in the bones of those men who have been inhaling quantities of fluoride that are far, far in excess of anything that we get at 1 part per million, over years with the amounts that they excrete in the urine, because if we know that a certain concentration would be present in the urine of a man who is showing some signs of change in the bone density, then we might be able to say how much might be possibly safely excreted in the urine of people who are getting the fluorine from drinking water. In that way we might establish a factor of safety, know how much more than 1 part per million we might have and still not get trouble.

Well, that work is not entirely completed and it cannot be for some time.

The CHAIRMAN. What is your conclusion on that?

Dr. HEYROTH. The conclusion would be that about 10 parts per million of fluoride in the urine seems to be the concentration excreted by the people who are beginning to show X-ray evidence of changes in the density of the bones; 10 parts per million in the urine, you see, is far above anything you are going to get in the cities where you

have 1 part per million in the water or even 5 parts per million in the water.

The CHAIRMAN. Mr. Jones has a question.

Mr. JONES. When you spoke of the workmen inhaling dust, they would be inhaling other things than fluorine; would they not?

Dr. HEYROTH. Probably not to a great extent.

Mr. JONES. They would be inhaling the gas then; is that right?

Dr. HEYROTH. It might be the gas HF—hydrogen fluoride gas—or it might be cryolite dust or superphosphate dust.

Mr. JONES. I was just wondering about the dust and the foreign matter that would be included in that inhalation probably.

Dr. HEYROTH. Probably nothing that would have a significant bearing on the experiment or the observations.

Mr. JONES. I see.

Dr. HEYROTH. There is a safe margin between trace quantities in drinking water which are required for optimal dental health and the amount which produces undesirable physiological effects. The most sensitive indication of the latter is interference with normal calcification of the teeth, which is manifested in mottled enamel, or edemic fluorosis. This effect, although compatible with caries-resistant tooth structure and, within certain limits, apparently with physiological well-being, is esthetically undesirable. The level of fluoride concentration in drinking water which is associated with the appearance of mottled enamel varies with individual susceptibility and with the amount of water consumed. The upper level of safety has been reached in the northern part of the United States in domestic water supplies containing approximately 1.0 to 1.5 parts per million fluorine, in the southern part of the country approximately 0.7 parts per million. There is no reason to believe that prolonged ingestion of drinking water with a mean concentration below the level causing mottled enamel will have an adverse physiological effect. Progress reports in several communities in which sodium fluoride has been added to the water supplies of low fluoride content indicate that this procedure will reduce the caries attack rate in children. There is evidence to suggest that it will confer an appreciable measure of protection of teeth of adults.

In view of these considerations, your committee recommends that any community which includes a child population of sufficient size, and which obtains its water supply from sources which are free from or are extremely low in fluorides, should consider the practicability and economic feasibility of adjusting the concentration to optimal levels. This adjustment should be in accord with the climatic factors and a constant chemical control should be maintained. With proper safeguards, this procedure appears to be harmless. However, it should be conducted under expert dental and engineering supervision by the State board of health. It should not be undertaken unless this can be provided. How much reduction in the prevalence of caries will actually be realized in a particular community will vary according to local conditions. The procedure will supplement but not supplant other dental health measures. About one-half of the population of this country is living in small villages and rural areas and will not benefit by fluoridation of public water supplies. Other provisions for preventing dental caries in this fraction of population should be continued and developed.

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Dr. Basil G. Bibby, director, Eastman Dental Dispensary.

Dr. H. Trendley Dean, director, National Institute Dental Research, National Institutes of Health.

Dr. A. McGehee Harvey, professor of medicine, the Johns Hopkins Hospital.

Dr. Francis F. Heyoth, associate professor of industrial toxicology and assistant director, Kettering Laboratory, University of Cincinnati, College of Medicine.

Dr. A. LeRoy Johnson, Former Head, Harvard School of Dental Medicine; dental consultant, National Research Council,

Dr. Harold A. Whittaker, professor of public health engineering, University of Minnesota School of Public Health.

Dr. Abel Wolman, professor of sanitary engineering, the Johns Hopkins University.

(References submitted by Dr. Heyroth in connection with his testimony are as follows:)

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The CHAIRMAN. Any questions, Mr. Kleinfeld?

Mr. KLEINFELD. Dr. Heyroth, were you here this morning when I referred to the article in the January 1952 issue of the American Journal of Public Health?

Dr. HEYROTH. I think I was but I am not sure it is the same one or not.

Mr. KLEINFELD. I would like to get your opinion on one or two statements here to see whether you agree or not. The first one is on page 46, and I quote:

> Most of the more recent articles emphasize the fact that sodium fluoride and sodium fluosilicate can be used interchangeably so far as the engineering aspects are concerned, giving no mention of the caries-reducing ability of the different compounds. The very obvious consideration in all these studies is whether or not compounds other than sodium fluoride will satisfactorily reduce human dental decay. If the only consideration in choosing a compound were its ability to furnish fluoride ions, then so far as the reagents suitable for use in public water supplies are concerned, almost any fluoride compound would probably suffice. This is implied in McClure's data. Using the fluoride compounds topically, this rationale is not correct, for when various fluorides are highly concentrated as they must be for use in conventional topical procedures, the ionization of the different salts is variable and certainly it is not complete. Thus, equivalents of fluoride ions may not be available.

Do you agree with that, sir?

Dr. HEYROTH. I think that is true, yes. I don't think that topical applications have great pertinence to the question of fluoridation of the water.

Mr. KLEINFELD. That is right. I have another paragraph here which I think is not directed to topical application. Let me read it. I think it may be of some length but it is rather significant.

> McClure compared the metabolic availability of fluorine as sodium fluoride and sodium fluosilicate by means of fluorine uptake in rat femurs and concluded that both of these fluoride compounds furnish similar amounts of the fluoride ion. No mention was made of their respective ability to reduce experimental decay. However, McClure commented on this subject by stating, "As additional data are obtained, particularly with reference to dental caries effects, conclusions

may be warranted regarding the possibility of substituting sodium fluosilicate for sodium fluoride, as a water fluoridating agent. The data accumulated thus far, however, do not justify any commitments in this regard."

Even though the evidence were available indicating caries reduction similar to that obtained with sodium fluoride, the results would not be indicative of what effect sodium silicofluoride might have in reducing caries in a developing tooth. In addition to this, Muhler, Nebergall, and Day have shown that some compounds reduce the incidence of decay in rats much more than sodium fluoride, yet the amount of fluorine deposited in the femurs is only one-third to one-half as much. It appears then, that other criteria besides the amount of fluorine available by analysis should be considered when evaluating new fluoride compounds.

What is your comment on that, Doctor?

Dr. HEYROTH. When was that published?

Mr. KLEINFELD. Well, the article appears in the January 1952 issue of the American Journal of Public Health and the Nation's Health.

Dr. HEYROTH. I believe there is a subsequent article written subsequently by McClure himself that has appeared in the Public Health reports. At least he told me that on the phone, and he believes now that the silico-fluoride does cause some caries inhibition in rats. However, I may not be quite correct in that statement. It is the impression he gave me.

Mr. KLEINFELD. The reason I ask, Doctor, is that it is the understanding of this committee that the District of Columbia, which is to fluoridate its water supply within the next few months, intends to use sodium silico-fluoride. Apparently from this article which appears in the January 1952 issue——

Mr. HEYROTH. Is that by Day?

Mr. KLEINFELD. This is by C. L. Howell, L. E. Burney, Harry G. Day, and Joseph C. Muhler.

Dr. HEYROTH. Yes.

Mr. KLEINFELD. Are they qualified people, do you know, Doctor?

Dr. HEYROTH. Yes. That is, Day is a biochemist. The others, I take it, are students.

Mr. KLEINFELD. Burney is an M. D., M. P. H., F. A. P. H. A.

Dr. HEYROTH. I have met Day.

Mr. KLEINFELD. Day is an Sc. D. Howell and Muhler have a D. D. S.

So that the conclusion of these people in what seems to be a very recent article, January 1952, appears to be that you cannot say that the effects of sodium silico-fluoride in reducing the incidence of dental decay will necessarily be the same as the effects of sodium fluoride.

Dr. HEYROTH. I think you are in the same situation there we were in when we started sodium-fluoride experiments at Newburgh and elsewhere: We didn't know sodium fluoride would do it at that time. That is why we started the experiments.

Mr. KLEINFELD. We don't know whether sodium silico-fluoride will do it, do we?

Dr. HEYROTH. So there should be similar experiments on children, on man, on the human. However, the evidence McClure is getting now seems to indicate it, and there is no theoretical reason why that shouldn't be the case.

Mr. KLEINFELD. Do you know whether that is published anywhere?

Dr. HEYROTH? What?

Mr. KLEINFELD. McClure's work.

Dr. HEYROTH. I think in the Public Health reports since the first of the year. I can't give you the exact reference. I think I am correct in that.

(The reference supplied subsequently is Zipkin, I., and McClure, F. J., Public Health Reports, 66: 1523 (1951).)

Mr. KLEINFELD. I see. This article refers to the May 1951, issue of Nutrition Reviews, which says in part this, and I quote:

On the basis of present knowledge, it would seem that use of any compound other than sodium fluoride for this purpose—

apparently the purpose of preventing or reducing the incidence of dental caries—

should be considered experimental until demonstration of the availability of the fluorine in that compound has been made in satisfactory human experiments.

That is, I think, what you just said.

Dr. HEYROTH. That is what I said, yes.

Mr. KLEINFELD. Doctor, your report to the city of Cincinnati recommending and endorsing the fluoridation of the city's water supply was issued on January 26, 1951?

Dr. HEYROTH. I think so. There should be a date.

Mr. KLEINFELD. The copy I have here on the first page seems so to indicate.

Dr. HEYROTH. Yes.

Mr. KLEINFELD. And the report of the ad hoc committee of the National Research Council on fluoridation of water supplies was made November 29, 1951, as I see it.

Dr. HEYROTH. Yes.

Mr. KLEINFELD. Are you familiar, Doctor, with the meeting of the ad hoc committee of the National Research Council on fluoridation of water supplies held on April 10, 1951?

Dr. HEYROTH. I was present.

Mr. KLEINFELD. That was held after you submitted your report to the city of Cincinnati, was it not?

Dr. HEYROTH. Yes, but the material in this Cincinnati report was presented in the course of the deliberations.

Mr. KLEINFELD. I see.

There are a few questions here I would like to ask your opinion on, if you don't mind.

On page 2 it is stated——

Dr. HEYROTH. Is that the minutes?

Mr. KLEINFELD. The minutes of the ad hoc committee, yes, sir. Do you have a copy?

Dr. HEYROTH. I think I have.

Mr. KLEINFELD. I will read it to you.

The CHAIRMAN. How long will you be?

Mr. KLEINFELD. I have a few questions unless you want to put it in the record and adjourn. Whatever the committee wishes.

The CHAIRMAN. What is your opinion? We are getting on here, it's a little late now. How long will it take you, Mr. Kleinfeld?

Mr. KLEINFELD. Perhaps 15 minutes.

The CHAIRMAN. Can we put it in the record?

Mr. KLEINFELD. I think the committee agreed to put the report itself in the record. Maybe we could put these minutes in the record, too.

The CHAIRMAN. Then if you had any questions and the doctor does not object, we can make that part of the record later.

Mr. KLEINFELD. Thank you.

Dr. HEYROTH. I should only add to that that any statements made in the minutes do not reflect the final deliberations and final conclusions, because the deliberations were all condensed to make a report somewhat like this [indicating], which was circulated among the members of the committee for their comment, and then alterations were made in the first one.

The CHAIRMAN. Can we follow that same procedure and let Mr. Kleinfeld ask you a few questions and you comment, and we will include it in the record? Is that all right?

Mr. KLEINFELD. In the meanwhile we will put them all in.

The CHAIRMAN. Mr. Jones.

Mr. JONES. You say these minutes as published there were just a condensation of what took place?

Dr. HEYROTH. Those were the minutes taken by the secretary.

Mr. JONES. I see.

Dr. HEYROTH. At the time of the meeting.

Mr. JONES. What did you say about——

Dr. HEYROTH. How complete or incomplete, I have no way of knowing.

Mr. JONES. You said that did not reflect——

Dr. HEYROTH. It is not final. The final action was not taken at the meeting. The final action was to condense what was said at the meeting into a report which could be presented. That was written and sent to all the members.

Mr. JONES. In other words, this report would reflect the final action?

Dr. HEYROTH. That is the final action, yes.

Mr. JONES. If that is the final action, I do not see any need of putting the minutes in the record.

Mr. KLEINFELD. Whatever the committee wishes.

Mr. JONES. What is your purpose of putting the minutes in?

Mr. KLEINFELD. I do not want to put them in. I would rather ask Dr. Heyroth a few questions if we have the time, concerning certain questions raised by various people at that meeting.

The CHAIRMAN. I do not want to impose on the committee or the reporter.

Mr. KLEINFELD. Certain doubts were raised there and it may well be they were resolved subsequently.

The CHAIRMAN. Go right ahead.

Mr. KLEINFELD. Do you want me to proceed?

The CHAIRMAN. Yes.

Mr. KLEINFELD. In these minutes, Doctor, a member of the ad hoc committee said—

he could see no danger from direct effects of fluoridation, but he thought it important to watch for subtle changes. He asked if an attempt had been made to study these effects in cities with fluoridation of water supply.

Dr. Heyroth said that such studies had not as yet been made.

Now, subsequent to that meeting, have you concluded that such studies have been made?

Dr. HEYROTH. Not except those two I have mentioned—one at Bartlett, Tex., and the other by Hodges.

But in the course of the discussion there, the matter of the industrial fluorosis was thoroughly discussed, and that member was convinced

by that, I am sure, because he agreed and signed the report, you see, later on.

Mr. KLEINFELD. I mean when this statement was made in April 1951, you said that such studies with respect to subtle changes in cities which were fluoridating their water supply had not been made.

Dr. HEYROTH. I think that is true, yes, in the Newburgh and the other. Now I understand from what Dr. Ast has said this morning that such studies are being made.

Mr. KLEINFELD. On adults?

Dr. HEYROTH. On adults, no.

Mr. KLEINFELD. Page 5 of these minutes reports that a member of the ad hoc committee said—

> that on the basis of the evidence presented he saw little danger in fluoridation, but would hesitate to recommend it universally at this time. He added that he felt that further studies should be made. He emphasized that there should be a note of caution in the picture.

What further studies was this member discussing?

Dr. HEYROTH. He did not specify what he meant. Evidently, though, he has been satisfied since he agreed with the report.

Mr. KLEINFELD. Do you know what particular data satisfied him subsequently?

Dr. HEYROTH. No, I don't.

Mr. KLEINFELD. Subsequently it is stated that another person present at the meeting said that a large amount of study had been given to this subject. He summarized as follows:

> 1. There is good evidence of decrease in caries in both deciduous and permanent teeth;
> 2. There exists no definite evidence of clinical injury or intoxication as the consequence of use;
> 3. There are certain areas in which difficulties not yet seen should be explored: (*a*) In the aged; (*b*) in individuals with renal involvement; (*c*) experimentation in regions where individuals eat a great deal of fish.

Do you know whether, subsequent to this suggestion, experiments were carried on anywhere in these categories?

Dr. HEYROTH. Dr. Ast mentioned this morning that some work on the renal phase of it was being done, still in progress, at Newburgh.

Mr. KLEINFELD. Was that not on children?

Dr. HEYROTH. In children. I am not so sure about the aged. However, I think this is true: That acute nephritis, as it might be induced in animals by the administration of a poison such as uranium, will decrease the ability of the animal to eliminate fluoride in the urine. That is true.

That raises the question—is it possible that in chronic nephritis in man that might be the case?

We have in the medical literature the case of a young man who had an extreme kidney involvement. He was in the Army. He died at the age of 22.

While he was in the hospital it was found, incidentally, that he had fluorosis, shown by X-rays. He did not have any bone impairment or anything of that sort. He died of kidney disease.

A dye was administered to him and none whatever was excreted by the kidneys. That means this man was in an extreme state of kidney disease.

He had lived most of his life in areas with very high content of fluorine.

That case is outlined in the Cincinnati report. Just because of that one case in the literature, I still feel that we need investigations of the ability of abnormal kidneys to excrete fluorides.

However, this is true: A man with such a severe impairment is not apt to live for a length of time that would permit the accumulation of sufficient fluoride in the bone to cause damage, and he would be treated by a physician, and the physician could state that he should not be given water with fluoride in it; just as in certain cases of kidney disease the physician says that a man should not take salt, no sodium in his diet.

We are dealing there with abnormal people, and we can't make general regulations that would apply to every case.

We don't prohibit sugar because some people can't take it because of diabetes and so on. We have got to look at the general welfare in an over-all picture.

Mr. KLEINFELD. Is it not true, Doctor, that you can live without sugar and, I suppose, without sodium chloride or salt, but you have got to have water?

Dr. HEYROTH. That is right.

Mr. KLEINFELD. So if a person in the District of Columbia is suffering from kidney trouble, I think your advice would be not to drink water.

Dr. HEYROTH. No, the advice would be to drink some water that comes from a mineral spring that is free from fluoride, which could be done.

This man is very sick, you see, and that is a prescription for him.

Mr. KLEINFELD. That is what he would have to do—he would have to get his water privately elsewhere?

Dr. HEYROTH. He would if it can be established that he is going to be sick for the rest of his life, which I doubt very much. He is either going to improve his kidney function and then that question is no longer pertinent, or else he is going to die, and then it is no longer pertinent.

Mr. KLEINFELD. Doctor, in your report to the city of Cincinnati dated January 26, 1951, on page 8, you say this:

> About 1946, workers of the United States Public Health Service expressed the opinion that fluoridation should not be undertaken until epidemiological data comparable in reliability to those secured in regard to the incidence of caries and mottled enamel had been obtained on the health of old people who had lived for long periods in areas of known high and low fluoride concentrations in the drinking water. Unfortunately, such data have not been provided, except to a very limited extent.

Is it not important that such data be provided?

Dr. HEYROTH. I think it is. I put it in this report for the purpose of stimulating that sort of work.

Mr. KLEINFELD. But you did recommend fluoridation?

Dr. HEYROTH. Yes, I did recommend fluoridation.

You see there we have a calculated risk. Whenever one has to make any decision of this sort—shall we or shall we not put fluorides in water—we have to see what is the risk on both sides. If we put it in, I think the risk of doing any systemic damage to the aged and so on is very, very remote. If we leave it out, we know what the risk is in regard to the dental caries that we are not going to eliminate in children.

Mr. KLEINFELD. I have no further questions.

The CHAIRMAN. Mr. Jones?

Mr. JONES. No further questions.

The CHAIRMAN. Doctor, I suppose I could ask you more questions, but we do not plan any further hearings at this time. I do not say that there may not be additional meetings of this committee. I mean public meetings. From the inception of the committee, after our organization meeting, every meeting has been open to the public, and we have attempted to have testimony before this committee from men of reputation and those who are recognized in their field.

However, we have received a great quantity of correspondence from the public at large, and we try to check up.

I think on behalf of the people who wrote in I should read one letter without mentioning the name of the writer, to show the concern of some people and perhaps ask a question or two of you. Maybe you can clarify the situation.

This is a typical letter but it goes into somewhat more detail:

> It has recently come to my attention that the District of Columbia water system, acting upon the advice of certain dental and medical sources and with the approval of the United States Public Health Service, proposes to add fluorine to the District water supply starting sometime during the month of April. This procedure, if it is undertaken, will so seriously affect the health and well being of the residents of the District of Columbia that I strongly urge you to exert your influence in delaying the innovation until all of the facts against the procedure can be ascertained.
>
> I am a biochemist and physiologist and for many years have maintained my own biochemical research laboratories in New York and Washington.
>
> About 12 years ago, while engaged in cancer research and experimentation in my New York laboratories, I discovered that two of the halogen group of chemicals, namely, iodine and fluorine, had considerable effect in the cancer process. I discovered that iodine is highly beneficial in combatting some forms of cancer, and that fluorine is very definitely and positively a procancerous material which promotes and speeds up all forms of cancer. I then conducted an exhaustive series of tests and experiments with fluorine to determine its effect on the human body and on foodstuffs.
>
> If there is any further information I can give you or your committee on the effects of fluorine and the advisability of its use in the water supply of the District of Columbia, I will be most glad to do so.

Now, upon receipt of this yesterday I called counsel, who contacted this gentleman. We discovered that he had apparently done a great deal of work, and while he had not written any papers, nor did he have any degrees, he seemed to have a lot of material and had spent a great deal of time on this, but for that reason I did not call him as a witness. I did not think it advisable.

But he raised some questions. Is there any comment you can made upon this statement of an ordinary citizen? He says, "Fluorine is definitely and positively a procancerous material which promotes and speeds up."

From your experience have you found that to be a fact, or have you any knowledge on that subject?

Dr. HEYROTH. The only thing I could say about that is that in the many papers on animal experimentation there have been no comments made about the production of any cancers as a result of the administration of fluorine in the diet.

The CHAIRMAN. Well, this man writes several things. I say I would have called him, but it has been the policy to take only those who are accepted somewhat as authorities.

He goes on to the question of teeth. Now he says:

Fluorine in the drinking water over a period of time, the period will be long or short in proportion to the age of the individual, and the condition of the heart muscles, can produce high blood pressure as fluorine acts as a constrictor on the lining of the arteries and blood vessels. This can produce a serious condition in persons who already have weak hearts.

Could you comment on that?

Dr. HEYROTH. I know of no evidence in favor of that statement. The examination of workmen who have been exposed for years had given no indication that that is the case.

The CHAIRMAN. Then he goes on to say, and I am only quoting part:

Perhaps the most characteristic feature of cancer from a biochemical standpoint is the definite deficiency in the respiration of cancer cells. Faster growing cancer cells show a greater respiratory deficiency than do the slower growing cells. Fluorine inhibits respiration in the cancer cell (probably in all other cells of the body) and thereby speeds up the cancer process. This fact was proved conclusively by an exhaustive series of tests I made in my cancer research laboratory some years ago.

Dr. HEYROTH. That last statement is true when one deals with high concentrations of fluoride. It does inhibit certain of the oxidative enzymes, but it has no relation to cancer. In those concentrations it has nothing to do with the concentrations that are used in the fluoridation of water. I can't believe that is pertinent.

I have seen some vital statistics which may or may not be admissible. I believe Dr. Miller did not prefer that type of evidence.

San Francisco has no fluoride in the water, and the cancer death rate there is practically the same, within statistical variation, as the cancer death rate at Denver, which has 1.2 parts per million.

The CHAIRMAN. He then says, and here is a definite statement:

Sodium fluoride destroys vitamin C and most of the members of vitamin D complex.

Can you tell us something about that?

Dr. HEYROTH. I don't believe that is the case, but I have no evidence.

The CHAIRMAN. Is there any way that you could help this committee through your association in determining this?

Dr. HEYROTH. One can't answer that sort of a statement unless one sees the evidence which he has amassed in favor of it. Otherwise it is merely a flat statement which may or may not be true.

The CHAIRMAN. That is why I did not call him to make this gentleman's testimony part of the record. This is one of the hundreds of letters that the committee and myself have received over the period of the last month or two on the subject, and these people seem to be concerned. For that reason we took every available authority that we could find, accepted authority, and asked them to testify at great length before this committee. I do not know what we can add to what has already been testified to over the period of weeks, particularly on this subject. We have called those who are available and recognized as an authority or have done any research work in the fluoridation of water.

That is why I say we will keep the possibility of further meetings open. Presently no further hearings are scheduled, and none are anticipated in the very immediate future. However, the committee will now go into executive session from this point on.

I must say that we are indebted to our reporter, Mr. Veley, among many of the other people. I note that he works here without relief and has followed this committee through more than a year of hearings. I have had some experience with reporters, but this man is tops. I know the committee is indebted to you for the fine work you have done here.

(Dr. Heyroth's report to the Cincinnati Board of Health referred to above is as follows:)

FLUORIDATION OF THE WATER SUPPLY IN THE PROPHYLAXIS OF DENTAL CARIES, ITS EFFECTIVENESS AND SAFETY [1]

I. DENTAL ASPECTS

Since dental authorities are in general agreement in regard to the relationships between the content of the fluoridation in communal water supplies and various types of dental disease, these relations are here summarized only very briefly. Further details are to be found in two symposia arranged by the American Association for the Advancement of Science (1) (2).

A. Mottled enamel

Prior to 1931, dentists who had been studying the condition known as mottled enamel had been impressed by the fact that its incidence was very high among children and young adults in certain communities in the Rocky Mountain and Texas areas, whereas it could not be found in those in other communities distant, in some cases, by only a few miles. In communities where it was endemic, it was present only in the natives or in those who had migrated into the area in early infancy and so had lived in them during the period of calcification of the enamel of the affected teeth. Teeth that had calcified prior to the migration of the persons into the area were unaffected (3). These epidemiological observations suggested that the condition was due to some element present in trace quantities in the drinking water. Proof of the water-borne nature of the condition was afforded in 1931, when it was found that the water of St. David, Ariz., a town in which all of the population had mottled enamel, when concentrated by evaporation to one-tenth its volume and fed to rats, induced a defect in their teeth that simulated mottled enamel. (Laboratory experiments also demonstrated that the addition of sodium fluoride to the diet of rats caused changes in their teeth suggestive of mottling.) At about the same time fluoride was found in the water of Bauxite, Ark., where the condition was severe. It was then looked for in the water from the wells at St. David and found present in concentrations ranging from 3.1 to 7.1 p. p. m. However, one well in that town had only 0.7 p.p.m., and no mottling appeared in those who used its water (4).

Dental surveys were soon made in many towns in various parts of the United States and, indeed, in many parts of the world, with the object of correlating the severity of the condition, expressed in terms of a widely adopted grading system, with the quantities of fluoride present in the water that induced it. Mottled enamel has been found in over 375 areas in the United States and in more than 175 in Argentina, as well as in Canada, Mexico, Africa, Japan, China, India, Australia, England, Italy, Spain, Holland, Greece, and Hungary (5). Typical of the observations were such as these: At Aurora, Ill., where the water contains 1.2 p. p. m., 4.7 percent of the permanent teeth had very mild or scarcely detectable mottled enamel, while 0.4 percent had it in mild degree. In another town in which the water contained 2.6 p. p. m., 74 percent of the permanent teeth were affected. It is now generally agreed that a few cases can be found through careful search by skilled examiners in communities using water with 1 p. p. m. There is some evidence that in hot regions in New Mexico, where the water consumption is high, the threshold may lie at 0.7 p. p. m., the incidence being 30 percent in those using water with 0.9 p. p. m. (6). Whereas Cincinnati water has about 0.2 p. p. m. (0.1 to 0.3), some waters in the United States have from 10 to 15 p. p. m. The waters in most extensive use in the United States have from 1.0 to 2.0 p. p. m., and the majority of the waters even in endemic areas

[1] A report presented to the Cincinnati Board of Health January 26, 1951, by Francis F. Heyroth, M. D., Kettering laboratory in the department of preventive medicine and industrial health, College of Medicine, University of Cincinnati, Cincinnati, Ohio.

have less than 4.0 to 5.0 p. p. m. (7). However, more than 1 million persons in 500 communities use water with more than 1.5 p. p. m., according to Faber (8). A limited number of analyses of Ohio waters have indicated that in 29 communities, including Kent and Lima, there were 1.0 to 2.0 p. p. m. in the water; in 17 there were 2.0 to 3.0 p. p. m.; and in 3 near Toledo there were 3.0 to 4.0 p. p. m. (9). Very large amounts have been reported in South African waters, many samples containing over 20 p. p. m., the highest reported value being 53 p. p. m. (5).

A normal human diet supplies from 0.3 to 0.5 mg. of fluoride daily, most foodstuffs containing about 1 p. p. m. (0.3 to 1.7), although a few, as sardines and tea, contain considerably larger amounts (7). Vegetables and cereals grown in endemic areas have no more than those grown in areas where the water is nearly free from fluoride (4). The fluoride in foods is much less important, generally, than that in water in the production of mottled enamel. There is, however, one interesting exception to this statement, and others may be found later. Mild mottling occurs among the natives of the island of Tristan Da Cunha despite the fact that the water contains but little fluoride, the chief source being the marine fish which form a large part of their diet (10).

In addition to the evidence from animal experimentation and from epidemiological surveys, further confirmation of the causative role of fluoride in mottled enamel has been furnished by the results obtained when certain communities in which the condition had been endemic changed their water supplies to one free from fluoride (3). Even before the cause was known, Oakley, Idaho made the change from a warm to a cold spring because one family free from the condition had been using the latter. The result was that after a period of 8 to 10 years, mottled enamel ceased to appear. Bauxite, Arkansas, made a similar change with a like result when it was found that its water contained 14 p. p. m.

B. The Caries-fluoride relation

For some time it was assumed that mottled enamel, a recognized cosmetic problem, was associated with other types of harm to the teeth. It was asserted (4) that caries was particularly bad at St. David, where the water had 3 to 7 p. p. m., all of the population over 21 having caries, and 50 percent of those over 24 wearing plates. On the other hand, as early as 1916, Black and McKay gained the impression that mottled teeth were less subject to caries than normal ones, although they believed that caries, once it started in such teeth spread rapidly (11). The impression that caries was less prevalent in mottled teeth was borne out by observations (12) in Japan, in the Argentine Republic, in Arkansas at Bauxite, in Idaho, and in Arizona at the Pima Indian School. Beginning about 1938, Trendley Dean of the United States Public Health Service began a systematic epidemiologic study of the question, and Cox approached it by animal experimentation. The results definitely showed that the incidence of caries is reduced when the water supply contains an adequate concentration of fluoride. In South Dakota (12), in regions where mottled enamel was generally prevalent, the caries rate was 201 per 100 children, in areas where its incidence was uneven and sporadic, the caries rate was 314, and where there was no mottled enamel, the caries rate was 415. In seven Wisconsin cities supplied with water containing almost no fluoride, the caries rate was two to three times that at Green Bay, where the water had 2.3 p. p. m. In the latter city, the rate in permanent teeth was 282 per 100 children, whereas in Sheboygan where the water had no fluoride, it was 854.

The ingestion of quantities of fluoride insufficient to cause cosmetic damage is capable of conferring resistance to caries. Galesburg, Illinois, with 1.9 p. p. m., in its water supply, had only one-third the caries rate of Quincy, Illinois, a town with the same climate, but with a water supply that contained only 0.2 p. p. m. A similar difference was found in the caries rates in 2 towns situated 2 miles apart in the Chicago area. Oak Park with no fluoride in its water had three times the caries rate of Maywood, with 1.4 p. p. m.

Waters with greater concentrations of fluoride confer little additional benefit. The results at Green Bay with 2.3 p. p. m. were no better than those at Kimberley with 1.2 p. p. m.

In a further attempt to make more precise the quantitative relationships, Dean (2) determined the indices of mottling in 21 towns with progressively increasing quantities of fluoride in their water over the range of 0.0 to 14.1 p. p. m. The indices of mottling ranged from 0.01 to a maximum of 3.4, the latter being indicative of a serious degree of damage in the entire susceptible population. When plotted against the fluoride content of the water, the values fell consistently

along a smooth S-shaped curve. In 1941–42, Dean extended his observations on caries to include 7,257 12- to 14-year-old white children in 21 cities in Illinois, Indiana, Colorado, and Ohio, and found a rate of 767 in those living in low-fluoride areas (0.0 to 0.2 p. p. m.) and 275 in those living where the water contained more than 1 p. p. m., a difference of 3 to 1. On the proximal surfaces of the four superior permanent incisors, the difference was 9 to 1. In 11 cities with less than 0.5 p. p. m., the caries rate was more than 700; in 3 with from 0.5 to 0.9 it was more than 400; in 4 with 1.0 to 1.4, it was 300, and in 3 with more than 1.4 it was 250. When the rates in the 21 cities were plotted against the fluoride content a smooth curve was obtained, the rates decreasing from 1037 in Michigan City with 0.1 p. p. m. to 236 in Galesburg with 1.9 p. p. m. When the curves for the incidence of mottled enamel and of caries are considered together, it is readily apparent that a concentration of 1.0 p. p. m. gives a strikingly low incidence of caries with only sporadic cases of the mildest type of mottling.

Further indications of the validity of the caries-fluoride relationship came quickly from other parts of the world, notably England (13), India, and South Africa (14). In the latter area, Ockerse found that the caries rate was 69 percent in children without mottled enamel and only 29 percent in those with that condition.

Additional confirmation has come from animal experimentation. Caries is produced in rats with difficulty and only by the use of a coarse diet. Its nature differs from that of human caries in that it affects chiefly the molars and is in part due to the formation of fractures. Despite these difficulties, it has been demonstrated (1) that the presence of sufficient quantities of fluoride in the diet of rats reduces the number of carious lesions, but the evidence from this source is less clear-cut than that from epidemiological surveys on man.

The epidemiological evidence led to the suggestion that fluoride be added to waters in which insufficient amounts are present. Before this could be recommended, some investigators regarded it as necessary to show that the addition to water of a commercially available inorganic fluoride would confer the same beneficial results as does naturally occurring fluoride. To prove this, experiments to learn the effects of artificial fluoridation were undertaken at Grand Rapids, Mich.; Newburgh, N. Y.; Sheboygan, Wis.; Midland, Mich.; and Brantford, Ontario. In several of these cases, a nearby city roughly comparable as to size and economic status and with a similar water supply was used as a control. A considerable number of localities are adding fluoride to their water supply nonexperimentally. In most instances, the fluoride is added in the form of the sodium salt. In Madison, Wis., a solution of hydrogen fluoride is used, and some cities propose to use sodium fluosilicate or hydrofluosilicic acid.

In general, the results reported to date have been favorable. It is still too early for the maximum benefits to be appraised, since none of the experiments was begun until 1945, and at least 8 years must elapse before a final evaluation can be made. Some of the data indicate that some benefit may have been found in groups of persons who were not subjected to the fluoride-containing water until after their first molars had erupted (15). Once the benefits of fluoridation have been secured, they appear to be permanent even though the person may migrate to an area where the water is deficient in fluorides (16).

No claims are made that fluoridation will completely eradicate caries, and no therapeutic value in respect to established caries is alleged. Other factors, as familial susceptibility, doubtless play a role. Despite a considerable amount of animal experimentation, it cannot be said that the mechanism by which fluoride in water inhibits the onset of caries is understood.

Authorities responsible for the health of communities might be regarded as negligent if they failed to take the necessary steps to provide their communities with water that contains the optimum amount of fluoride for dental health. On the other hand, they would be equally open to criticism did they fail to investigate carefully the possibility that by altering the fluoride content of the water they might inadvertently affect the general health of the public because of some hitherto unsuspected deleterious effect of fluorides on parts of the body other than the teeth. It is, therefore, necessary to examine carefully the evidence pertaining to the toxicity of fluorides.

II. THE TOXICITY OF FLUORIDES

The poisonous nature of sodium fluoride is a matter of common knowledge, since it is widely used as a roach poison. A few years ago in Pittsburgh, powdered sodium fluoride was accidentally used in place of baking powder in the kitchen of a large dining room with the result that 52 persons became ill and

11 of them died (17). However, the acute toxic effects of fluorides have little, if any, bearing upon the hazards associated with the presence of fluoride to the extent of 1 p. p. m. in drinking water, and any hazards that may arise from the fluoridation of water will be those that result from the cumulative action of fluorides.

That a form of chronic systemic intoxication by fluoride (fluorosis) exists was demonstrated by the occurrence in Morocco of a disease of animals known as darmous, an affection of the teeth and mandibles of sheep and cattle, pastured on soil contaminated by dusts of phosphate deposits that were high in fluoride content (18). In volcanic regions of Iceland the disease also occurs and is there known as gaddur. In a more severe form, the condition has also occurred among animals in the vicinity of plants manufacturing superphosphate fertilizers or reducing aluminum from its ores. In some instances the condition simulates osteomalacia, and has been called fluorine cachexia. Mr. Largent of the Kettering Laboratory has investigated a case in which cattle had been exposed for 5 to 9 years. Their gait was stiff-legged, their hock joints were swollen, and lumps were palpable on the metatarsals, metacarpals, and ribs. Their teeth were irregularly worn, and their milk output was deficient. That they had stored excessive amounts of fluoride was demonstrated by the fact that 6 months after removal from the area one of the cows continued to excrete daily amounts of fluoride greatly in excess of those ingested in the diet.

In order to learn something of the quantitive relationship between the daily intake, its duration, and the development of signs of poisoning, a great many experiments have been performed in which various fluoride-containing compounds have been incorporated at various levels in the diet of animals of several species. It is unnecessary to record here the detailed results of each of these. Dependent upon the level of the dietary intake experimental animals have shown various types of response.

At levels above 0.09 percent of fluoride in the diet, rats die after a few days to a few months, following a period of inanition characterized by lethargy and weakness. When the food contains lesser amounts, but more than 0.03 percent, an unhealthy appearance with lessened appetite and growth is usually noted. Levels greater than about 0.011 to 0.023 percent cause some inhibition of growth, the effect increasing rapidly with increasing fluoride content in the food.

Only at levels of dosage (15 to 30 mg. of fluoride per kg. of body weight of animal per day) high enough to produce impairment of growth have histological changes in the organs been reported by most who have searched for them.

Ingested fluoride is stored chiefly in the bones and teeth. Little is stored in most of the soft tissues, with the possible exception of the thyroid gland.

In the Kettering Laboratory, two litter-mate dogs were given 65 mg. of fluoride daily, one as sodium fluoride and the other as cryolite, over a period of 65 months. These amounts were equivalent to 3.2 to 4.1 mg. per kg. per day. No skeletal abnormalities could be detected by X-ray examinations, and no signs of illness appeared, except in the case of a third litter-mate which was given no fluoride. When the animals were killed no striking abnormalities could be found in their bones. Similar observations have been made by Biester, Greenwood, and Nelson (19). On the other hand, the bones of rabbits fed for 47 to 92 days on a diet that contained from 245 to 763 p. p. m., or, in some cases, 2,980 p. p. m. (equivalent to from 12 to 50 mg. per kg. of body weight per day) showed numerous small areas of abnormal porosity, along with placques on the mandible, ranging from wart-like exostoses to extensive general deposits (20). There was also a bulking of the mandibles with a bulge on the medial surface slightly below the margin of the molars. None of these changes could be detected by radiological examinations during life. The fluoride content of these bones was about 17 times the normal value.

Chronic fluorosis has also been found to occur among men exposed in industry to dusts containing large amounts of fluorides. While investigating the incidence of tuberculosis and silicosis among Danish workers with cryolite, Moller and Gudjonsson (21) unexpectedly encountered an increased density in the X-rays of the bones of 30 of 78 of these men. The condition was studied thoroughly by Roholm (22). Two cases are recorded in the United States medical literature, one being that a 58-year old man who had been exposed for 30 years to sodium fluoride as a dust (23). The other was that of a man who had had 18 years of exposure to rock phosphate dust (24). The latter, who was in a hospital because of luetic aortitis, had exhibited no arthritic symptoms, but careful examination revealed some slight limitation of motion

of the lower spine. The other had complained only of fatigue and headaches. Members of the staff of the Kettering Laboratory have examined the X-rays of a large number of men long employed in three factories in which they were exposed to considerable amounts of both hydrogen fluoride vapor and fluoride-containing dusts and have found a considerable number of cases of fluorosis.

The X-rays showed as initial changes an abnormal density with the trabeculae increased, thickened, and blurred. This appeared in all bones, but especially the vertebral column and pelvis. Spicule formation was sometimes seen at the muscle attachments which, like the spinal ligaments, were sometimes calcified. In one of the Danish cases, ankylotic changes had progressed to a degree which caused a very severe impairment of function. In the United States no pain or discomfort was found in association with the development of the bony changes, which occurred very gradually, and the condition when slight had no effect on the productivity of the worker or on his life expectancy. Of Roholm's (22) patients, 53 percent suffered nausea and loss of appetite, 46 percent had shortness of breath, and 28 percent had localized rheumatic pains. Some were anemic, and it has been suggested that this may have been due to the encroachment of the bone upon the marrow cavity. There is no evidence that disability has ever preceded the development of changes detectable by radiographic means.

Numerous cases of human skeletal fluorosis attributed to an unduly high content of fluoride in the drinking water have been reported to have occurred in several parts of the world. At Yunnan, in China, four or five cases have been described involving elderly persons who drank water containing 5.9, 6.3, or 13.1 parts per million. Malnutrition may have been a contributing factor (25). Systemic poisoning has been found by Ockerse (5) in South Africa where the fluoride content in the water is often extremely high. Six natives exposed for 19 years to water with 11.78 parts per million had characteristic X-ray changes and stiffness of the lumbar, thoracic, and cervical regions, while 2 years of exposure to 9.3 parts per million caused detectable changes in the bones of a European. A large number of cases have been reported to have occurred in the Madras Presidency in India, where the water has from 2 to 10 parts per million, but the reports are difficult to evaluate, because of the lack of control observations in other fluoride-low areas or because malnutrition was prevalent, or because many of the diagnoses were made without the evidence afforded by X-rays. Furthermore, the high temperatures in the region may have increased the daily intake of water.

A series of at least nine cases has been reported to have occurred in the Argentine Republic (26). In one, death was due to uremia, and the bone ash was found to contain 0.97 percent of fluoride. There is much uncertainty as to the fluoride content of the water consumed by the affected persons. In many areas in the Argentine Republic it exceeds 2 parts per million, and in one, it was known to have been 16 parts per million.

In the United States only one case has been attributed to the fluoride content of the drinking water (27). It was that of a 22-year-old soldier who had lived most of his life in several regions of high-fluoride content. From birth, he lived for 7 years in a region where the fluoride content of the water was 12 parts per million. Subsequently, he lived for 2 years where it was 5.7 parts per million, and then for 7 years where it was 4.4 parts per million. After a break of 2 years, during which he lived where the content was low, he again spent 7 years in the regions where it was 4.4 parts per million. The condition was found incidentally during a stay in a hospital following a minor operation. Anemia and severe kidney disease were also present. In a test for kidney impairment, no dye was excreted in 2 hours. Uremia developed and the patient died. At necropsy, the findings were chronic bilateral pyelonephritis, acute right pyonephrosis, and bilateral hydroureter with ureteritis. In this case, no stiffness of the spine was present, and the question was raised as to whether the kidney disease had so interfered with the normal excretory mechanism for fluorides as to make the rate of storage abnormally great. (Rabbits suffering temporarily from experimentally induced uranium nephritis excrete greatly reduced quantities of fluoride in their urine during the period of the acute intoxication, while being maintained on a high intake of fluoride in their drinking water (28). A somewhat similar case (29) is that of a young woman in Argentina with bilateral uretero-hydronephrosis and complete extrophy of the bladder, who died at the age of 23 after having exhibited the radiologic signs of fluorosis. Knowledge of the fluoride content of the water she ingested is lacking.

The cases of chronic fluorosis ascribed in the literature to the presence of fluoride in the water provide little reliable information as to the threshold

value at which harmful storage may be expected to begin. In 1940, McClure (29) was of the opinion that water containing from 3 to 16 parts per million could not be regarded as safe until further epidemiologic evidence had been provided.

III. EVIDENCE BEARING ON THE SAFETY OF FLUORIDATION

About 1946, workers of the United States Public Health Service expressed the opinion that fluoridation should not be undertaken until epidemiologic data comparable in reliability to those secured in regard to the incidence of caries and mottled enamel had been obtained on the health of old people who had lived for long periods in areas of known high and low fluoride concentrations in the drinking water. Unfortunately, such data have not been provided, except to a very limited extent. Hodges (30) found no X-ray evidence of fluorosis in 86 subjects ranging in age from 7.5 to 71 years who had been exposed, in some instances, so long as 61 years to the water of Kempton, Ill., which contains from 1.2 to 3 parts per million. He also examined 31 subjects who had had from 18 to 68 years of exposure to the water of Bureau, Ill., which contains 2.5 parts per million, and again found no generalized skeletal sclerosis. However, in testimony offered at the Food Residue Tolerance Hearings on Cryolite in 1944, Dean stated that a radiologic survey at Bartlett, Tex., where the water contains 8 parts per million, revealed an incidence of 11 percent of cases having increased bone density, but no impairment of function. This survey does not appear to have been published.

McClure (7) found that the number of fractures reported by 1,450 high-school boys and by 1,700 draftees bore no relation to the fluoride content of the water of the areas in which they had lived. Furthermore, careful pediatric observations, including X-ray studies, on the children in the Newburgh experiment have failed thus far to demonstrate any deviation from normal skeletal maturation and no increases in radiologic density (31). However, data obtained on children or young adults have little bearing upon the problem of chronic fluorosis in the aged.

The incidence of kidney disease, at least in young men, does not appear to be greater in areas where the water has a moderately elevated fluoride content. In 101 samples of the urine of young men living in areas in which the water had 2.0 to 5.0 p. p. m., no more instances of occult blood, albumin or sugar were found than in 394 specimens from men living in areas with 0.0 to 0.3 p. p. m. (7).

Studies of the metabolic fate and storage of ingested fluorides offer further evidence as to the safety of fluoridation. On the assumption that 1,200 to 1,600 cc. of water represents the average daily intake of water in temperate climates, the daily intake of fluoride in water with 1 p. p. m. would be 1.2 to 1.6 mg. Children up to the age of 12 might ingest 0.8 to 1.1 mg. When the water contains 4 to 5 p. p. m., the daily intake by adults might be 4.8 to 8.0 mg., or 0.07 to 0.12 mg. per kg., and Biester, Greenwood, and Nelson (19) estimated that the intake in areas where the water contained 8 to 10 p. p. m. might be so much as 0.45 mg. per kg. It has been estimated that the affected Danish cryolite workers may have ingested 25 to 30 mg. daily for long periods (22).

From brief balance studies upon human subjects, McClure (7) was of the opinion that when the amount ingested daily does not exceed 4 or 5 mg., the excretion of fluoride in the urine and perspiration is great enough to prevent the storage of significant amounts in the skeletal tissues. However, the results of balance studies on human subjects in the Kettering Laboratory suggest that storage may begin at a somewhat lower level than that found by McClure. That considerable storage occurred when 6 mg. in addition to that from dietary sources was ingested daily for 183 days was shown by the fact that during the succeeding 11 weeks the excretions contained about 50 percent more than was ingested in the normal diet. The observations on one of the subjects indicated that during a period of 3 years more than 2 g. had been stored in his bones. Some of our more recent observations indicate that the efficiency with which fluoride is eliminated may increase when the ingestion of abnormal amounts is continued for long periods.

Data on the urinary excretion of fluoride by exposed workers offer the most satisfactory evidence for the safety of fluoridation. Urinary concentrations associated with various degrees of fluorosis and those which appear to be safe may with some assurance be compared with those encountered among large groups of persons living in areas where the water contains known fluoride concentrations.

The average urinary concentration found by Roholm (32) among cryolite workers was 16 p. p. m., the range being 2.4 to 43.4 p. p. m. in proportion to the severity of exposure. In our industrial surveys, questionable fluorosis was found in some men with urinary concentrations of 3.8 mg. per liter, but others with no signs of fluorosis gave an average concentration of 4.8 p. p. m. The urine of men with moderate fluorosis had, on the average, 5.5 mg. per liter, while that of those with severe fluorosis averaged 6.8 mg. per liter.

McClure (7) made over 1,900 determinations of the urinary fluoride concentrations of high-school boys and draftees and found that when the water contained from 0.2 p. p. m. to 4.7 p. p. m. the urinary fluoride concentration closely approximated that in the drinking water numerically. When the drinking water contained less than 0.2 p. p. m., most of the urinary fluoride was derived from that contained in the diet. No observations were made by McClure on persons living in areas with water that contained more than 4.7 p. p. m., but Machle (33) found some evidence that where the water contained 8.1 p. p. m., the urinary concentration tended to be 6.4 mg. per liter or somewhat less than that which would have been predicted by extrapolation from McClure's data. Prior to fluoridation of the water at Grand Rapids (0.1 p. p. m.), 264 samples of urine from 12–17-year-old boys contained, on the average, 0.2 p. p. m. One month after fluoridation to 1 p. p. m., 315 samples contained 0.65 p. p. m.

From these data it appears extremely unlikely that the presence of 1 p. p. m. in water would give rise to urinary concentrations which have been associated with detectable changes of the bones in industrial workers.

Additional evidence is afforded by the results of fluoride determinations in the bones of a few persons known to have had chronic fluorosis. According to Roholm (23), normal human bones contain on the average 0.09 percent of fluoride (range 0.06 to 0.21 percent), while 2 of his cases of fluorosis had bones with 0.65 to 0.72 percent. The long bones of the case of Wolff and Kerr (34), who had nondisabling fluorosis, contained 0.18 to 0.29 percent, while the ribs, sternum, and vertebra had from 0.56 to 0.70 percent. They concluded that the skeletal tolerance was of the order of 0.2 to 0.3 percent of fluoride.

The complete retention of all of the fluoride ingested in the form of drinking water containing 1 p. p. m.—most of this would be excreted—would result in the storage of about 0.5 g. per year, and in the course of 80 years, the total amount stored might be 47 g. This represents about 1.0 percent of the weight of a human skeleton, a value only 3 to 5 times the skeletal tolerance of 0.2 to 0.3 percent estimated from the data of Wolff and Korr. The crude calculation is in rough agreement with the other lines of evidence.

The question of the effect of water containing 1 p. p. m. upon patients with severe impairment of kidney function requires special consideration in view of the fact that radiologic evidence of chronic fluorosis has been found in 2 persons with severe kidney disease who died at the early ages of 22 and 23 years, respectively. It is very likely that the life expectancy of persons with a degree of functional impairment of the kidney great enough to increase significantly the rate of storage of fluoride would be too short for skeletal damage involving functional impairment to become manifest. However, this question has not been adequately studied. It is highly desirable that in a region where the water contains 1 p. p. m., determinations of the ability of the kidney to excrete fluorides be made on large numbers of hospitalized patients with chronic kidney disease of various types and degrees of severity, and that the results be compared with those obtained upon healthy persons. In any event, the risk that such patients might be harmed by the fluoridation of water appears to be small in comparison with the dental benefits to be obtained. It should be possible for psysicians who have the care of patients with severe chronic kidney disease to recommend the use of imported fluoride-free water should this be necessary.

In general, consideration of the available evidence indicates that the risk to the public health from fluoridation of the water is negligible. Nevertheless, it is desirable to consider by what means any harmful effects of fluoridation might be detected in the population as a whole before the manifestations of chronic fluorosis had progressed to a disabling degree. Dental examinations among school children would certainly reveal the occurrence of mottled enamel long before any skeletal effects could be expected to become manifest. That persons who had migrated into the community after their enamel had calcified might develop fluorosis without exhibiting mottling is of little importance, because if the water were capable of so affecting them it would certainly cause mottling in the children. Determinations of the urinary fluoride concentrations at intervals of a few years might serve as an additional safeguard. There is some difference of opinion as

to whether early bony changes would be detectable on the small films used in X-ray surveys for tuberculosis, but the radiologists at the Health Center would, in all likelihood, be able to detect them on large films.

The possibility that there may be other sources of fluoride than the water supply must be considered. Industries in which actual cases of disabling fluorosis have occurred do not exist in Cincinnati at present, although the lesser hazards encountered in magnesium founding and in the handling of sodium fluoride may exist to some extent. It seems incumbent upon industries possessed of such hazards to eliminate them by bringing their fluoride exposure within currently accepted safe limits.

Fruits and vegetables may be contaminated with residual fluoride dusts following the use of fluoride-containing insecticides in orchards and fields. The control of such fruits and vegetables as may enter interstate commerce lies in the province of the United States Food and Drug Administration which in the near future will set a tolerance limit compatible with the presence of 1 p. p. m. in the drinking water.

In cities where fluoridation of the water has been introduced, there have been no complaints of significance from industrial users of the water, and no harm to lawns or plants has been seen. The taste of the water is unaffected. Insofar as fluoride contributes nothing to the value of water used for purposes other than drinking, an element of wastefulness is involved. It is perhaps for this reason that the American Water Works Association believes that the cost of fluoridation should be covered by funds allocated by municipalities for the promotion of health rather than be made a charge against the user.

Some have objected to fluoridation on the ground that it represents "involuntary mass medication." This term is not an appropriate one, for no claims are made that fluoridation of water exerts any therapeutic action. It cannot bring about a repair of the damage wrought by caries. It might be called mass prophylaxis, but even this is not an entirely suitable term since it might imply, to some minds at least, that some foreign substance is being added to the water. Actually all that is proposed is that the concentration of a substance naturally present in the water supply be increased to a level which has been demonstrated to be optimal for dental health.

The attorney general of the State of Michigan has given an opinion (6) that, once authorities responsible for the public health have approved fluoridation, there would be no legal method by which an individual not injured by it, but nonsympathetic to it, could prevent it. As to liability, he states that it would involve no change in the responsibility of the utility. Negligence in performing the fluoridation which results in damage would have to be shown in order to establish liability. Either under- or over-fluoridation might be construed as negligence.

Should fluoridation be undertaken, adequate precautions should be taken to insure the safety of employees at the water works who may be engaged in the handling of the fluorides. The charging of the hoppers is a dusty operation, and while so engaged the operators should wear suitable toxic dust respirators. Dust collectors consisting of bag filters operating under positive air pressure vented to the outside have been recommended. Some observations should be made to learn whether the contamination of the air in the neighborhood exceeds safe limits and, if so, methods for preventing it should be adopted.

Determinations of the fluoride content of the air in the Sheboygan plant during actual operation have revealed that the only place in which amounts in excess of those regarded as safe were found was in the breathing zone of the operator while emptying a barrel or sodium fluoride into the hopper. The urinary fluoride concentrations of the operators were not significantly higher than those of unexposed employees.

MOTION

I move that the board recommend to council that the water works be directed to adjust the fluoride content of the city water to that which is optimal for dental health, by the addition of a fluoride-containing compound of such nature and in such amount as the board may specify and in accordance with such procedures and with such analytical controls as may be prescribed by the board to insure the safety of the public and of the workmen engaged in the process.

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The CHAIRMAN. Mr. Kleinfeld.

Mr. KLEINFELD. I have two documents here, which I think you have copies of. A few weeks ago the Manufacturing Chemists' Association, which is the trade association for the chemical industry, recommended that several documents be inserted in the record, which was done. They have now asked that an additional document, called "The MCA Approach to Proposed Changes in Present Law," be inserted into our record.

I recommend that it be done in conformity with their suggestion.

The CHAIRMAN. I know of no objection.

Mr. JONES. I have no objection.

The CHAIRMAN. Without objection it is so ordered.

(The document referred to is as follows:)

THE MCA APPROACH TO PROPOSED CHANGES IN PRESENT LAW

The Manufacturing Chemists' Association, Inc., after a detailed review of existing legislation and various proposals for new legislation relating to chemicals in foods, has reached the following conclusions:

1. *Existing legislation* vests the Government with adequate authority over the use of chemical additives. In other words, the Government already possesses the means of obtaining adequate information and also possesses all of the remedies that are needed, in order to enable the Government to cope with any situation that may arise *after a chemical additive has been placed in use.*

2. *Existing legislation* is also adequate to assure that *advance information* is supplied by industry to the Department of Agriculture, with respect to *proposed new uses* of pesticides.

3. The one area where it can be argued that present law may need strengthening is in assuring that *advance information* is supplied by industry to the Food and Drug Administration, with respect to *proposed new uses* of chemical additives.*

4. As a matter of practice, both the food industry and the chemical industry today supply the Food and Drug Administration with a substantial volume of information, on a voluntary basis, with respect to *proposed new uses* of chemical additives. Speaking to this point in an address which he delivered on September 19, 1951, Commissioner Crawford of the Food and Drug Administration said: "It would not be too much to require by law that all food producers live up to what is being voluntarily done by the conscientious majority."

5. Under the circumstances, the Manufacturing Chemists 'Association recommends that consideration be given to new legislation containing the following provisions:

(*a*) On and after a given date (July 1, 1952, for example) there shall be no new use of any chemical additive in or on any food, until 60 days after a notice of such intended use has been filed with the Food and Drug Administration.

(*b*) The notice of intended use may be filed by either the chemical manufacturer or a food processor.

(*c*) The notice of intended use shall report the applicable pharmacological and toxicological data available. The notice of intended use shall also report the known composition of the chemical additive, a method for the determination of how much of the chemical additive is in or on the food, and directions for the use of the chemical additive with respect to the specific food and the specific use that is proposed.

(*d*) The notice of intended use shall be accompanied by samples of the chemical additive.

(*e*) Within the 60-day period between the filing of the notice of intended use and the date when actual use may begin, the Food and Drug Administration may re nest the person or persons filing the notice of intended use to appear at its offices in Washington or elsewhere, for such conferences or discussions concerning the intended use as may be appropriate.

6. Under this proposal, once the chemical additive has been placed in use, the Food and Drug Administration will be in a position, in those instances where circumstances so require, to exercise the authority it possesses under existing legislation as discussed in Section 1 above.

7. In our considered judgment, based on 18 months of study by our Committee on Chemicals in Foods and on numerous consultations with representatives of the food industries, the suggestions set out above represent a fundamentally sound approach to this important problem. We invite the constructive suggestions of governmental agencies, the food industries, the public, and any other persons with a contribution to make in this vital and complex area.

Mr. KLEINFELD. The last thing I have is a letter dated February 25, 1952, from the General Federation of Women's Clubs which recommends that pretesting legislation with respect to chemicals in foods be enacted. I suggest, if the committee concurs, this letter be made a part of the record.

* As used in this proposal, and for the reasons outlined above in the discussion of pesticides, the term "chemical additive" does not include substances covered by the Federal Insecticide, Fungicide, and Rodenticide Act of 1947.

The CHAIRMAN. Without objection it is so ordered.

Mr. JONES. If we start doing that, are we going to establish a policy of accepting letters from every organization that wants to express an opinion on what should be done without any more apparent basis than this club has?

The CHAIRMAN. I would say "No." Our practice has been to deny it, but I think the Federation of Women's Clubs sent its representative here to testify and testified at some length and under cross-examination, and under the circumstances I think they are entitled to express the opinion of the majority of that organization. I believe that most everyone will recognize them as a reputable group of women who are trying to do what they consider best for the health of the nation.

Mr. JONES. I have no question about their intentions. There may be some doubt about their information.

The CHAIRMAN. This is not professional advice, it is merely a recommendation; that is all. If you have objection, we will take it up with the committee.

Mr. JONES. I would rather take it up with the committee.

The CHAIRMAN. All right, we will reserve opinion on that and hold it in abeyance until such time as the entire committee can meet.

Is there anything else?

Mr. KLEINFELD. I have nothing else, Mr. Chairman.

The CHAIRMAN. All right, the committee will stand adjourned subject to the call of the Chair.

(Whereupon, at 1 p. m., the committee recessed subject to the call of the Chair.)

(The following statements were submitted for the record:)

THOUGHTS OF LOUIS SCHWARTZ, M. D., ON PRETESTING COSMETICS BEFORE DISTRIBUTION AND SUBMITTING SUCH TESTING DATA FOR APPROVAL TO THE FOOD AND DRUG ADMINISTRATION

[Biography of Louis Schwartz, M. D., Washington, D. C.: Jefferson Medical College, M. D., 1905; Medical Director, United States Public Health Service, retired; adjunct clinical professor, dermatology and syphilology, New York University; assistant professor, dermatology and syphilology, Georgetown University; coauthor of Cosmetics and Dermatitis; consultant to members of the cosmetic industry]

I wish to preamble my remarks by stating that I feel highly honored to be asked to express my opinion before this congressional committee and that I feel deeply the responsibility which it places on me.

In my opinion cosmetics as a whole, as made in the United States, are safer today than ever before. When it is considered that by far the large majority of people in the United States use cosmetics in one or more forms, the percentage of cases of dermatitis reported from them is almost infinitesimal and the percentage of systemic poisoning or other bodily injury outside of dermatitis is even less.

Face and body powders, creams, toilet soaps, dentifrice, shaving preparations, and baby oils, which constitute a large part of the cosmetics used, are today practically innocuous.

Cases of irritation which may occur from their use are rare and are on an allergic basis.

By far the large majority of reported cases of dermatitis has been attributed to preparations used on the hair, preparations used on the lips, and preparations used on the nails.

The chief offenders among the hair preparations have been the hair dyes, hair wavers and straighteners, hair tonics, eyelash dyes, hair lacquers, and, recently, hair shampoos.

Let us discuss briefly the damage reported from each of these hair preparations.

The dermatitis from hair dyes has been attributed chiefly to the para dyes. The peak of the reported cases occurred in the early 1930's. Since 1937 very few cases have been reported.

Recent statistics show that the incidence of reported cases of dermatitis from para containing hair dyes is about 1 to 80,000, whereas in the 1930's it was of the order of 1 to 10,000. This great reduction is in my opinion due to the purity of the paraphenylenediamine now used, to the greater care used in making the oxidizing solutions, to the lower content of ammonia now used, to the requirement of a predyeing skin test and to the power the Food and Drug Administration has to seize cosmetics which cause harm.

Hair wavers, especially the cold wave and particularly the cold wave for home use, have been reported as causes of loss of hair, and there are two reports of systemic poisoning from their use.

Most of the cases of dermatitis and hair loss reported from the cold wave occurred in the early days of its use. The hair loss was temporary and the report of one investigator of five cases of mild toxicity among beauty-parlor operators due to inhaling the fumes of the thioglycolates is open to question. The other report was a fatality due to the peculiar and unusual method of using ammonium sulfide as a hair waver. This chemical and method of waving has not been used since that time.

Today the cold wave is widely used both at home and in the beauty shops and cases of dermatitis from it are rare indeed, and there have been no more reports of systemic poisoning.

This is due to improved methods of manufacturing and the lower content of ammonium thioglycolate, lower alkalinity, and improvement in the technique of application.

What I said about hair wavers applies in a measure to hair straighteners mostly used by colored people, although some hair straighteners contain strong alkalis and resins.

There was one outbreak of dermatitis from a hair lacquer made during World War II by a small manufacturing concern. It could not obtain shellac which they formerly used and substituted a synthetic resin of the glyptal type containing maleic anhydride. They did no pretesting for possible skin irritation before selling it and the outbreak of dermatitis followed. The Public Health Service investigated and found the synthetic resin to be the cause, and it has not been used since then.

Shampoos have but rarely been blamed for causing dermatitis, yet they consist of soaps and synthetic detergents, both of which can cause allergic dermatitis. This because they remain on the scalp for a short time and in high dilution.

Recently two cases of corneal opacity have occurred from shampoos which accidentally got into the eyes and which contained one of the new synthetic detergents. No such cases had been reported before. Since the irritant properties of the synthetic detergents are not well known, in the future all shampoos containing them should be tested for possible eye irritation before being sold to the public.

Hair tonics have often been the cause of dermatitis. They may contain such well-known irritants as resorcin, canthraides tar, etc., which may well cause dermatitis and eye damage if any of the tonic accidentally gets into the eye. Yet hair tonics are widely used and the incidence of skin damage or eye irritation is low.

Eyelash dyes containing paraphenylenediamine were reported in 1936 to have caused eye damage. As a result, the para dyes are no longer permitted in eyelash preparations and cases of eye irritation from eyelash preparations have not been reported since then.

LIPSTICKS

The use of lipstick in the past 20 years has become almost universal among women living in civilized countries. Yet the cases of cheilitis or dermatitis attributed to them are rare.

The first case of cheilitis from lipstick in the United States was reported in 1935 and was attributed to allergy to a synthetic perfume ingredient, methyl heptine carbonate. Later reports attributed the cheilitis to photosensitivity induced by the indelible fluorescent dyes belonging to the eosin group, and one observer reported dermatitis from allergy to the metallic container of the lipstick. Since 1940 reports of cheilitis from lipstick have been rare. Manufacturers now use dyes of higher grades of purity and pigment lakes which protect the lips from the rays of light.

Nail lacquers and nail lacquer bases have been reported to have caused allergic dermatitis. Here again if we consider the number of women using nail lacquers, the incidence of dermatitis is rare and must be due to allergy to some ingredient of the nail lacquer.

Nail lacquers have been in vogue for about 15 years. Sulzberger as early as 1937 reported hypersensitivity to nail polish. Reports of cases appeared in the literature more frequently, the peak being reached in 1940–41. The dermatitis in most cases appeared on the face, neck, and other parts of the body which is habitually stroked by the fingers and most of the cases were attributed to allergy to the phenolic resin and the dye contained in the nail lacquer. From 1944 to 1948 very few if any cases of dermatitis from nail lacquer were reported. In 1948, there was an outbreak of damage to the nails from nail lacquer bases which contained a phenolic resin, synthetic rubber, a plasticiser, and a solvent.

The dermatologists reporting these cases attributed the cause to allergy to the phenol formaldehyde resin. Inquiry into the frequency of the reported cases showed an incidence of 1 to 61,000 packages sold. This seems to confirm the theory of allergy.

Dermatitis has been reported from other cosmetics such as perfume, powder, sun-tan preparations, etc., but they are more or less medical curiosities.

The incidence of allergy to something or other among the general population has been estimated as of 1934 at from 50 to 60 percent. In 1941 the National Retail Dry Goods Association canvassed its member stores and found that 110 stores reported 486 complaints of dermatitis from customers which they attributed to fabrics, and the same 110 stores reported only 61 complaints of dermatitis from customers which they attributed to cosmetics. From this we can deduce that cosmetics are at least as safe as fabrics. In my experience there seems to be a considerable percentage of people who are allergic to some article of common diet, such as fish, cheese, strawberries, tomatoes, and even milk and eggs. These facts indicate to me that cosmetics today as a whole are as safe to use as most other substances in common use.

This in my opinion is due to—

1. The present laws regulating their manufacture and use.
2. The care exercised by most manufacturers to make safe cosmetics so as to encourage the public to use them.
3. The availability of pure chemicals from which cosmetics are made.
4. The rigid testing of cosmetics required by the casualty insurance carriers before they will carry the liability insurance.
5. The power of seizure of harmful cosmetics possessed by the Food and Drug Administration.
6. The generally accepted use of the prophetic patch test as devised by me, or some modification of it.

The only weakness in these tests lies in the person who performs them. Cosmetic manufacturers should employ dermatologists experienced in cosmetic testing to perform the skin tests. Some now employ inexperienced dermatologists, or dermatologists who delegate the actual performance of the tests to subordinates or even to technicians. Some employ testing laboratories or industrial foundations to test their products and there the actual testing may be performed by inadequately qualified personnel. Some cosmetic concerns consider a favorable result from the patch tests sufficient evidence to place their product on the market. They overlook or ignore the actual usage tests which is an important part of the pretesting procedure advocated by me as part of the prophetic patch test.

The fact that, despite such misuses of the prophetic patch tests, dermatitis from cosmetics occurs so infrequently, is proof of the value of the test and the adequacy of the present laws regulating the sale of cosmetics.

Nevertheless, if there would be some law requiring all cosmetic manufacturers, large and small, to rationally test cosmetics containing untested chemicals or new formulations as is now done by many cosmetic manufacturers to determine their safety before placing them on sale, it would add another safeguard to protect the public. However, if the test procedures were also dictated by the law, then in my opinion the cosmetic manufacturers who observed the law might be absolved from the responsibility for allergic reactions and toxicity of their products which they now bear, and the Government would have to assume it.

A Memorandum on the Dangers of Cosmetics and the Testing Methods by Which Such Dangers Can Be Foretold

By Adolph Rostenberg, Jr., M. D.

[Biography of Adolph Rostenberg, Jr., M. D., University of Illinois, Chicago, Ill.: McGill University, M. D., 1931; practicing dermatologist, New York City, 1933–38; dermatologist, Food and Drug Administration, 1939–45; associate professor, dermatology, associate director, allergy unit, University of Illinois]

It would seem that in order for the committee to be able to fulfill the functions for which it was set up, it would need to know the kinds of injuries arising from cosmetics, the extent to which these occur, the various classes of cosmetics, and the chemicals in them which are most prone to cause damage, and, finally, methods of testing by which such injuries can be foretold as well as the defects in such methods. Parenthetically, it might be stated the word "cosmetic" in this report is used in the dermatologic sense of the term, which is not identical with the way the word is defined in the F. D. C. Act.

The types of injury can be classified into—

(1) Toxicologic reactions, acute or chronic
(2) Primary irritant reactions
(3) Sensitization reactions
(4) Pyodermic reactions
(5) Pigmentary reactions

By a toxicologic reaction is meant a reaction which arises because of some quality inherent in the substance which will cause injury to the majority of persons adequately exposed. Such reactions can be acute or chronic. In the case of cosmetics, the acute ones are rather rare, but they have been reported. For example, some years ago there was a death following the use of a solution of the cold type in permanent waving. This solution contained ammoniacal sulfides and allegedly sufficient was absorbed so as to produce an acute sulfhemoglobinemia. Actually, there was some argument as to the true cause of death in this case. This is not now too important, as the case is merely being cited as an example of a possible type of injury. Manifestations of chronic toxicity from the use of cosmetics are obviously more difficult to put one's finger on because of their somewhat insidious characteristics. There is reasonably well documented evidence to show that paraphenylenediamine and its derivatives can cause a variety of toxic manifestations after protracted use. Some of the manifestations which have been reported are optic neuritis, various types of nerve injuries, and anemia from damage to the bone marrow. Mercury is another drug which is known to have cumulative effects. Cases are on record in which there was central nervous system damage from the long-continued use of freckle creams containing mercury.

As to primary irritation, most cosmetics when used properly are self-evidently not primary irritants, but occasionally cosmetics such as eye lash and brow dyes, most of which contain ammoniacal silver salts, may cause a mild conjunctivitis. Depilatories containing chemicals which attack keratin are of necessity mildly primarily irritating inasmuch as the external layer of the skin as well as the hair will be affected.

Most of the reactions seen after the use of cosmetics arise because of the development of an allergic sensitization which is usually of the eczematous variety, but any kind can occur. While this is not the place to go into the theory of sensitizations, it would seem important that the committee have some understanding of the mechanisms involved inasmuch as this is one of the most difficult problems that they will have to consider. The factors influencing the development of a sensitization can possibly best be illustrated by the following bit of algebraic symbolism:

$$A^q \cdot G^a \geqslant k = S$$

A=the intrinsic allergenicity of the compound in question
q=quantitative factors affecting the allergen
·=times
G=the genetic make-up of the individual to whom the allergen is applied
a=adventitious factors which happen to be operable at the time the individual meets the allergen
$\geqslant$=means equals or exceeds
k stands for some hypothetical constant
S=clinical sensitization

The equation then indicates that the product of the intrinsic allergenicity of the compound modified by quantitative factors and the genetic make-up of the host modified by adventitious factors must equal or exceed some hypothetical amount to yield evidence of sensitization. From this schematic representation it is obvious that when a strong sensitizer, say poison ivy, is encountered no particular genetic background is required. On the other hand, with a weak sensitizer such as timothy pollen, most people do not become sensitized unless they come from an appropriate genetic stock. Before leaving this subject, it might not be amiss to state that the factors that determine whether or not a compound is likely to be highly allergenic are in a large measure unknown.

It should also be pointed out that while the term "sensitization" in this connection is primarily employed to designate an allergic sensitization, there are other types of sensitization, such as photosensitization. Certain cosmetics, particularly perfumes which contain oil of bergamot, are likely to predispose to the development of this. It is manifested by the development of a hyperpigmentation at the site of the application of the perfume. This type of reaction is known as a berlocque dermatitis.

The terms "a pyodermic reaction" is used to designate the development of a pyogenic infection at the site where a cosmetic was applied or where a previous cosmetic reaction occurred. Certain cosmetics seem to favor the development of this type of injury. Specifically, astringent antiperspirants apparently conduce toward the development of follicular bacterial infections probably by virtue of sealing organisms within the sweat ducts. Skin that has been the subject of an allergic eczematous reaction seems less well able to withstand various ordinary pathogenic micro-organisms.

Pigmentary reactions are uncommon and probably not too important. The long-continued use of mercurial-containing cosmetics may cause a cutaneous discoloration which allegedly is due to the deposition of metallic mercury in the skin. A rarer example is the accidental dyeing of one part of the body from the colors in a cosmetic used elsewhere. For example, some years ago the author and Dr. Dan Dahle reported a case where a woman's hair was dyed by virtue of the bleeding of a lake used in her face powder.

My next point is the extent with which injuries occur. It is obviously almost impossible to give any figure on this inasmuch as the vast majority of such cases are not reported. It is possible that examination of the files of products liability insurance companies might give some information, but for a variety of reasons it is not anticipated that data gathered in this way would be too accurate.

Of all the cosmetics used, it is this writer's unqualified opinion that paraphenylenediamine and paratoluylenediamine and their minor modifications are far and away the most dangerous of all cosmetics. Of other cosmetics, nail cosmetics are ones that are fairly likely to cause reactions because of the development of an allergic eczematous sensitization.

The final and most important point is a consideration of the means by which reactions might be foretold. In general, there are two major ways for such prophesying. First is the use of some sort of test, other than actual use, on animals or humans employing a relatively small sample. There are two inherent difficulties with tests designed to foretell what harm, if any, will result from the widespread use of a certain cosmetic. The first is a biological difficulty, and the second a statistical one. The biological difficulty arises because no test recapitulates exactly the actual conditions of use and hence the likelihood of reactions occurring under the conditions of the test and under conditions of actual use are not necessarily the same. Even if by some means the biological difficulty could be obviated, the statistical difficulty would remain. This is true for all biological experimentation. The following illustrates what is meant by the statistical problem. Suppose it was found that feeding a certain dose of a chemical to 10 rats produced liver damage in 2 of them. How many rats would be injured if the same dose were fed to 10,000? In other words, is the true percentage of damage 2 percent, or did by chance the sample of 10 contain 2 rats that were unusually susceptible or 8 that were unusually hardy? The second method consists of actual use tests on a limited population. This eliminates the biologic difficulty but does not solve the statistical problem. It has the drawback that it exposes the individuals to the full damage whatever its nature may be. It is thus seen that the technique to be employed and the ability with which reactions can be predicted will depend on the type of reaction under consideration.

In the case of acute toxicologic reactions, short-term animal studies utilizing

techniques which are well known to the pharmacologist should reveal accurately the likelihood of this manifestation. Chronic toxic reactions are more difficult to foretell, but, on the other hand, are not a too likely occurrence. Actually, the pharmacologist could probably make some prediction from the chemical nature of the compound as to the possibility of such occurring. However, in the case of entirely new compounds the only test known to me would be rather long term animal experimentation. It should, of course, be realized that any test designed to predict the development of such eventualities must take into consideration the conditions of use for the cosmetic in question. For example, the intraperitoneal injection of a chemical might reveal that it had a chronic toxicity, but would that be relevant if the chemical were contained in a depilatory which was to be applied to the skin surface, say, once a month? On the other hand, if the intraperitoneal injection tests failed to show any chronic toxicity it would be a reasonable assumption that the use of that same chemical in a depilatory would not cause the development of a chronic intoxication.

Tests for primary irritation are rather easy to devise, but, again, one must consider the proposed methods of use for the cosmetic. For most purposes 100 standard closed patch tests done on people who presumably have had no previous exposure to the cosmetic in question should suffice. The tests should be read at 24 hours and all should be negative. The reason for suggesting that they be applied to persons who have not had previous exposure is to eliminate the possibility of sensitization reactions. It should be realized that the degree of irritation engendered by mild primary irritants will vary greatly with the technic of testing used and with the environmental conditions at the time the tests are done. A very illuminating and thorough study on these points was done by Holland et al. at the Army Hygiene Laboratory and reported under the title of "Prophetic Patch Test" in the Arch. Derm. and Syph. for April 1950. It is strongly urged that the committee read this article in the original. It will be evident that for any uniformity in such testing so that comparisons between the results obtained by different workers can be made it is essential that the environmental conditions under which the tests are done be taken into consideration. It is to be stressed that cosmetics when they are primary irritants will be mild ones and the results of testing with them are very likely to be influenced by the above factors. On the other hand, it should be pointed out that testing under closed patches is probably more likely to provoke irritation than is the contemplated use of the majority of cosmetics.

When it comes to tests which allegedly will predict the likelihood of the development of allergic sensitizations, we are in a very difficult and uncertain position. It should be clearly realized that there is no absolute answer to this question. The only answer is a statistical probability. This probability can theoretically be determined to any degree of accuracy desired, but from the practical side it should be realized that to determine this probability with any high degree of accuracy requires very large samples. I think for a better understanding of the statistical aspects of this problem the committee should acquaint themselves with two articles, namely:

1. Henderson, C. R. and Riley, E. C.: Certain Statistical Considerations in Patch Testing, J. Invest. Dermat. 6:227, 1945.

2. Knudsen, L. F.: A Note on the Statistical Probabilities of Finding Hypersensitive Subjects in Random Samples, J. Invest. Dermat. 6:231, 1945.

For the purpose of predicting sensitization reactions, a technique that has had much publicity is the Schwartz-Peck prophetic patch-testing technic. This in brief consists of applying 200 patch tests and then repeating the tests on the same 200 individuals after an interval of about 3 weeks. If there are no positive reactions on the second application, it is judged that the article is safe for trial use. In view of the publicity and semiapproval that this technic has received, I should like to discuss it in a little detail. In line with my previous remarks, two questions are immediately apparent: (1) Biologically, how likely is this technic to sensitize? (2) Statistically, how much can one say from a sample of this size? In general, I believe it is safe to assert that the likelihood of sensitizing by this technic is far less than is the likelihood of sensitizing by using most cosmetics as they are recommended. It is probable that only the very strongest sensitizers would be picked up by this procedure.

Even assuming that the technic were capable of causing sensitizations as frequently as actual use and that there was no evidence of sensitization in the 200 test subjects what then could one say? According to Henderson and Riley, all that one would be in a position to assert is that it is unlikely that the product when used on a very large sample would cause reactions in more

than 1½ percent of the people to whom it was applied. In other words, the test is likely to give one a meaningless belief in the lack of the potential allergenicity of the product in question. Again referring to Henderson and Riley, one would have to test 46,083 subjects and obtain no reactions in any of them to assert at a 99-percent confidence level that if the product were used on an infinite population not more than 1 in 10,000 people would develop an allergic reaction to it. By a 99-percent confidence level is meant that the prediction that not more than 1 person in 10,000 would react would be wrong not more than 1 time in 100.

What methods can then be employed to predict the likelihood of an allergic sensitization developing? In view of the previous discussion it seems to me that the results obtained by any patch-test method that is practicable is meaningless in that it fails either to duplicate the conditions for the development of a sensitization or statistically it fails to give one an estimate that has any real value. If then a product passes the test for primary irritation, I believe that in order to discover whether or not a sensitization is likely to occur resort must be had to supervised use tests. For these to have any meaning it is essential that they be done under strict medical supervision and accurate records kept. I believe that the product should be used on a minimum of 100 people for a minimum period of 3 months during which time at least four applications of the cosmetic applied in its customary manner and at its customary intervals should be done. The subjects are, of course, to be closely inspected throughout the entire period for evidence of reaction. In the case of cetrain cosmetics, such as hair dyes, this procedure will have to be somewhat modified as the 3-month time period will not provide for four applications at the usual intervals. If the cosmetic passes this test without any evidence of sensitization developing it has at least cleared the biologic hurdle of not having produced sensitization under the contemplated conditions of use. However, statistically, there is not more information than with the same number of patch tests. It is therefore suggested that when the cosmetic passes the above it be given a further use test on, say, 1,000 subjects, but that these need not be medically supervised, which would materially reduce the cost. In order that these tests have some meaning, it is suggested that the cosmetics which are sold or distributed during the unsupervised use test be required to bear a numbered card corresponding to a number on the packaged article. These cards would be filled out by the user, being dated at the time of distribution. The cards would furnish information as to the name and address of the user, the number of times the article had been employed, the intervals between applications and any reactions noted. It could be required that the manufacturer submit 1,000 such filled-in cards to the Food and Drug Administration. While it might be difficult to get consumer cooperation, it is felt this could be worked out in a number of ways; for example, a filled-out returned card could have a certain refund or discount value.

To sum up then, it is realized that all tests designed to foretell the likelihood of the occurrence of an eczematous sensitization are fraught with difficulty and uncertainty. It is felt, however, that if a cosmetic passes seriatim (1) the test for primary irritation, (2) the supervised use test, (3) the unsupervised use test, the chance of any significant injury arising when the article is used on a large segment of the population is materially reduced. Finally, it is pointed out that patch tests for this purpose are very inefficient and in this writer's opinion practically worthless.

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